

Vocabulary Task Force

Draft Transcript

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Presentation

Judy Sparrow – Office of the National Coordinator – Executive Director

Good morning, everybody, and welcome to the Clinical Operations Workgroup Taskforce on Vocabulary. Just a reminder that this is a federal advisory committee, which means there will be opportunity at the close of the meeting for the public to make comments, and also a reminder to the taskforce members to please identify yourselves when speaking. We have a number of taskforce members on the phone this morning, but I'll begin with having the members here at the table to briefly introduce themselves. Chris Brancato.

Chris Brancato – Deloitte – Manager, Health Information Technology

Chris Brancato, Deloitte Consulting, contractor to the Office of the National Coordinator.

Donna Pickett – NCHS – Medical Classification Administrator

...Center for Health Statistics, alternate to Marjorie Greenberg.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Jamie Ferguson, Kaiser Permanente.

Betsy Humphreys – National Library of Medicine – Deputy Director

Betsy Humphreys, National Library of Medicine, National Institutes of Health.

John Klimek – NCPDP – VP Industry Information Technology

John Klimek, NCPDP.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

Stan Huff with Intermountain Healthcare and the University of Utah in Salt Lake City.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards

Chris Chute, Mayo Clinic.

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant

Floyd Eisenberg, National Quality Forum.

Patricia Greim – VA – Health System Specialist: Terminology

Patricia Greim, Department of Veterans Affairs, alternate to Linda Fischetti.

Judy Sparrow – Office of the National Coordinator – Executive Director

And I believe, on the phone, we have Donald Bechtel. Is that correct?

Don Bechtel – Siemens Medical – IT Architect, Standards & Regulatory Mgr.

Yes, that is correct.

Judy Sparrow – Office of the National Coordinator – Executive Director

Bob Dolan, are you there? John Halamka? Andy Wiesenthal?

Andy Wiesenthal – Kaiser Permanente – Exec. Dir. CIS

I'm here.

Judy Sparrow – Office of the National Coordinator – Executive Director

And Marc Overhage, are you on? Did I leave anybody off that roll call?

Jim Walker – Geisinger Health Systems – Chief Health Information Officer

Jim Walker, Geisinger.

Judy Sparrow – Office of the National Coordinator – Executive Director

Right. Thanks, Jim. And I'll turn it over now to Jamie Ferguson and Betsy Humphreys.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Thanks, everybody, and welcome to this session of the Vocabulary Taskforce of the Health IT Standards Committee Clinical Operations Workgroup. Our topic today broadly is the rules of the road for vocabulary subsets and value sets in meaningful use. At the end of the day, ideally, we'd like to be able to answer three questions in this regard: what must the federal government do, what should the federal government do, and what should the federal government not do with regard to these vocabularies?

We really do want to focus on meaningful use here today, and achieving those program goals will require achieving a level of semantic interoperability. This means having consistent implementation of vocabulary capabilities by eligible professionals and hospitals across the country, and many believe that this adoption will be facilitated by making a starting point available from the government, in addition to the defined requirements for quality and other mandated reporting programs, which again leads us back to the three questions of what should, must, or should not the government do in this regard.

Today in our session, we're going to start with definitions of subsets and value sets for vocabularies, and we're going to have three panels. We have a panel from EHR vendors representing a broad spectrum of different kinds of potential meaningful users as their customers and their user base. We're going to discuss those requirements. We also have a panel for terminology service providers where we can learn what best practices there are, what to avoid, and what they've learned from implementing and providing these services.

We also have a panel from the standards development organizations, the message standards developers where we can hear how they can integrate vocabularies in binding vocabularies into messages and what else they have learned in this regard so that we can develop those rules of the road. We're going to then have a committee discussion, taskforce discussion. We really do want to focus that at the end of the day, again, on focusing within meaningful use on what should the government do, what must the government do, and what should the government not do in developing governance and rules of the road for these vocabulary implementations.

At this point, I'm going to hand it over to Betsy Humphreys, who will walk us through the definitions that we've developed and propose priorities for our work.

Betsy Humphreys – National Library of Medicine – Deputy Director

Basically when the taskforce started its discussions, we realized that we better have working definitions for subsets and value sets because, depending on who was talking when, it wasn't clear that we were all talking about the same thing. So just so we start this with at least the working definitions that the

taskforce agreed to, so we know what we mean by this, then we'll be able to, I think, be sure we're understanding the comments that follow.

Not surprisingly, a vocabulary subset is basically a terminology set that is a subset of a standard vocabulary. That's how we're referring to it, and has been defined for some purpose, and the key ones are to either produce or contribute to a value set to define the universe of relevant values in the standard vocabulary for a specific purpose without necessarily constraining all possible values for that purpose.

Let's take an example of a problem list set where you could define, from a standard vocabulary, all the things in that vocabulary that could possibly be considered a patient problem, but you might find that the controlled vocabulary didn't actually have the thing you needed. That is that there was some new condition or something that wasn't there. And we would certainly not necessarily be requiring that a clinician not record what was really wrong with the patient just because the correct set within the standard vocabulary didn't cover that concept yet.

Then we feel that there are such things as convenient subsets, that is, things that actually facilitate implementation, perhaps provide direction to what are the most high priority things in the local terminology to be mapped to the standard terminology, what kinds of things might be preferred or given primacy and data entry in order to make things easier for clinicians using the system. And the two kinds that we have been talking about are frequency based subsets, that is where you actually have a set of data from across types of institutions, and you say these are the most frequently occurring tests, problems, or so for. Then others would be specialty based subsets where specialty groups would define pieces of the vocabulary that were likely to be of greatest interest to specialists in a particular field.

A value set is a slightly different animal, although it can be a subset, obviously. It's basically all the valid vocabulary values for a defined purpose. Value sets can be defined by reference to pieces of controlled vocabulary that is making a reference to a part of a hierarchical structure if a vocabulary is specified or has one, or they can be actually enumerated sets, so these are the N number of things that are valid for this particular purpose, or it could be a combination of those two, actually, in defining the set. So two primary things that are of interest to us are all the valid values for specific data elements or segments of standard messages, and another thing that is particularly of interest in the context of meaningful use is a value set that defines a parameter that is needed to identify a specific population within a group of health records, for example. And the example that is maybe first on our minds for this is to define the denominator and/or the numerator for a quality measure that might be required under meaningful use.

In discussing what the priorities were for the vocabulary taskforce, we felt that our priorities were convenient subsets that can aid meaningful use, value sets for meaningful use—excuse me, that should be quality measures—and value sets for parts of messages that are required for meaningful use. We also felt that another priority is focusing on agreement potentially on some detailed clinical models for some high use priority cases because that would help to constrain the kinds of vocabularies needed for those purposes, maybe address some of the pre- and post-modification issues, and so forth, so that's just by way of introduction.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

So now with the modification to the slide that's being displayed so that number two really should say value sets for meaningful use quality reporting, quality measures.

Betsy Humphreys – National Library of Medicine – Deputy Director

Exactly. Sorry.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Can we have a little bit of discussion on the taskforce if these are indeed the right priorities? I think this is something that we've discussed pretty much in this order, but I just want to get some feedback and validation from the taskforce members that this really is our focus. Yes, Chris?

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards

I think the general scope is correct. However, I would quibble with the order. I think we discussed previously that convenient subsets, while of interest, perhaps should not be our first priority. I do see their value, and I do see having them as a consistent contribution to implementers. But clearly, I think, just about everything that follows would have a priority. And the notion of identifying subsets that are useful and clinical implementations should perhaps be last.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Okay.

Andy Wiesenthal – Kaiser Permanente – Exec. Dir. CIS

Jamie, this is Andy. Boy, I was going to sit tight, but I can't after that. None of the other subsets can have any use unless the systems get implemented. In my own experience, and I'd urge Jim, who is on the call, and others to comment is that you can't implement without the first. You can't. They just won't use it very well. And so, without the convenient subsets, you can't get at any of the others. And that's, I think, for me, why it would have to be first priority.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Okay. Others? Floyd?

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant

That actually, I guess I'll be right on the fence with that to say that I agree with both of the prior comments that you need the convenience set to start.

M

...diplomat.

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant

The challenge is, in creating the value sets for individual quality measures, there's sometimes concepts that are not in the existing convenience sets, so those value sets might actually extend some of the concepts beyond the convenience sets that are currently available. And they need to in order to....

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

So that sounds like an argument, Floyd, for having essentially two number one priorities, which would be the convenience sets plus any additions that are required for the quality measures. Okay. Chris?

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards

While I don't disagree with the esteemed Dr. Wiesenthal, it seems prudent that to define what convenience sets are, one has to have an understanding of what the underpinning required sets are before you can even define convenient subsets of them, so it's the sequential ordering kind of thing. I fully agree that unless there's utilization, there's going to be no uptake. However, the very fact that we're having these hearings and that the country is all atwitter over vocabulary as a consequence of ARRA and HITECH implementation suggests, that implementation is possible given the incentives and, I guess, negative incentives as well for failing to adopt. So I'm less concerned about implementation, and I'm

more concerned about clarity and the ultimate goal of interoperability from which we can then designate, if you will, convenience subsets for implementation.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

I think it's also useful to differentiate between two different kinds of convenient subsets that we've discussed that I think Betsy talked about, but aren't exactly on this particular slide, and that is frequency bases subsets. Maybe it was on the previous slide. That is the differentiation between the frequency-based subsets that folks who are just starting out may want to have as a starter set. That would get to Andy's point of easing the implementation versus other subsets that are for the convenience of particular departments or medical specialties that I would personally agree with you would be a lower priority in my view.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer

This is Jim Walker.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Yes.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer

I think we probably all agree that there's got to be an iterative quality to the development of convenient subsets that would be – the subsets would be used to make it easy and attractive to use health IT and the value sets for meaningful use. I think the one thing we're going to want to watch is that a convenience set that will enable implementation and enable meaningful use that goes beyond what we've defined as meaningful use for 2011, 2013, or 2015. That convenience subset is going to need to be larger than just what our technical definition of meaningful use is, if it's really going to enable clinicians, the healthcare team to work more effectively. And so, we're going to need both to make sure that the value sets for meaningful use, as defined thus far, is supplemented with the kind of thing Andy is talking about, which is enough terminology that it will really help the organization work effectively in ways it hadn't been defined officially as meaningful use yet.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Okay. Other comments on the priorities here, other thoughts, any other thoughts on this? Okay. Thank you very much for that discussion. We're just a few minutes ahead of schedule now, and I think we're ready to start with our first panel, so if we could take just a minute and invite the vendor panelists up, then we can have both hear their testimony and have discussion.

Thank you all for coming here today on relatively short notice. I appreciate it very much, and we all do, and we're anxiously looking forward to this discussion. I think, first up, we have Dr. Ingram.

James Ingram – Greenway Medical Technologies – CMO

Good morning. I'm James Ingram. I'm a physician and chief medical officer at Greenway Medical Technologies. We're a nationally recognized EHR and offers a CCHIT certified ambulatory solution. We've been solely focused on this industry since 1998.

Greenway supports over 1,900 ambulatory practice sites across the nation representing close to 20 million patients on record in 30 specialties. Greenway also supports an adoption rate for our certified EHR at more than 90% of the clinicians actively using our system at the point of care.

I appreciate the opportunity to address the vocabulary taskforce today, focusing on convenience and value sets. The challenge for an EHR vendor has been to incorporate a vocabulary at the point of care

that we can adequately capture the essence of the patient's problems and medical history. I sit before you today not as an expert in vocabulary concepts, but to share my expertise in finding a solution for improving the text to codified data requirements for documenting a patient's visit.

From our start in the industry over 12 years ago, our focus has been on developing an integrated and interoperable solution that clinicians would use in a meaningful way long before meaningful use morphed into its current proposed definition. With an increase in quality reporting needs, the requirement for standardized clinical vocabulary becomes even more important. Despite having ready access to SNOMED vocabulary through UMLS, we found it challenging to fully implement this vocabulary into our particular design, as others have also found.

What we have learned is that the controlled medical vocabulary still has its challenges with pre- and post-coordinating concepts, as well as search tools at the point of care. Because of the difficulty using standard reference terminologies at the point of care, we have implemented a modified clinical vocabulary based on ICD-9, CPT-4, HCPCS, and First DataBank. Over the last year, we have focused more of our attention on developing a clinical interface vocabulary through a partnership and experienced medical terminology company. By using SNOMED as its base, along with the referenced vocabularies, and the ability to add local concepts from our sites in our master vocabulary based on SNOMED mapping, we will then make the system markedly more effective in reporting clinical relative data.

When looking at the vocabulary requirements for an EHR, perhaps the biggest challenge is having a system that provides clinical interface terminology functionality. We have come to understand that this is the most reasonable way to provide increased usability for any member of the clinical team. With the interface terminologies, there will be more effective use of reference terminologies to capture appropriate clinical information. This is more than just convenience sets, in my opinion, but having synonym terms that have enhanced the convenience set utilization at the point of care. Additionally, when dealing with different types of medical practices, and especially potentially using an EHR, we see the importance of recognizing the flexibility of grouping different convenient sets.

Another factor in the equation is movement towards personal health records. The PHR will also require patient interface terminology. The vocabulary will be more focused in lay related medical terms that would convert clinical terminologies and subsequent to reference terminologies. As with most EHRs, the preference would be to have all practices using the same lexicon so that semantic interoperability could be achieved. We welcome the decision to have a centralized entity, which would manage and support a suitable, standardized vocabulary, mapped to clinical and patient interface terminologies that could be used across a collected medical environment.

Now I would like to address some of the questions. Due to time constraints, I will address the first question, who should determine the subsets. With the numerous reference terminologies currently available, we suspect that the vast majority of subsets or value sets have already been identified. As an EHR vendor, we will look towards the terminology organizations to recognize the needs of the current day practice of medicine and provide frequently updated vocabulary for simulation into electronic healthcare record industry. From our perspective, it does not appear that we are short of terminologies, only that we have a challenge in a clinical environment to adequately use the terms to capture the essence of the clinical encounter with the patient.

Number two, who should produce subsets? From an EHR vendor standpoint, we look towards the reference terminology and consensus standard entities to provide this to us.

Number five, in what format that we would use? Currently, we can consume XML into our product. However, the future, there is a possibility of moving more towards sharing value sets. This profile has been identified by IHE in the value set repository. Our work within IHE has given us an opportunity to appreciate the approach would work well with multiple terminologies, providing their value sets through a value set repository where EHRs can consume them into our applications.

Number eight, what lessons have we learned? Approximately four to five years ago, our initial focus regarding controlled vocabularies was with the laboratory results using LOINC observation codes. We came to appreciate that across the spectrum in a clinical laboratory, there was a marked lack of reporting LOINC codes in their electronic reports. We focused initially on two of the major national labs.

During our evaluation, we realized that even within their respective systems, the consistency of LOINC reporting was a problem. Therefore, we approached this with a different manner, basically developing a clinical interface terminology approach. The laboratory companies provide the LOINC map results compendium that we use in our primary comprehensive value set. Subsequently, we compare the frequency information supplied by the companies, as well as surveying our sites to develop the typical clinical subset applicable across our 30 subspecialties using that service. Then, for any other labs that were interfaced with, which our system did not map to, we were able to provide a utility at the practice level for them to manually map the results that equals to the two mapped compendiums to create a new result.

I did respond to the other questions within the written testimony. But, due to time, I would like to stop at this point. Thank you very much for having me here today.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Great. Thank you very much. I think, next, Dr. “Rēd-r”.

Jacob Reider – Allscripts – Chief Medical Informatics Officer

Vocabulary, it’s “Rīd-r”, actually.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Thank you.

Jacob Reider – Allscripts – Chief Medical Informatics Officer

Maybe that’s a piece of metadata that we need is the correct pronunciation. That didn’t count against my time today. Thank you, Jamie. Or is it “Hīmē”?

I’m Jacob Reider. I’m the chief medical informatics officer from Allscripts, and as you all say, politically challenged. Allscripts is an interesting vendor in that we have four electronic health records products currently in use. So, as I said in my written testimony, we’re a little bit of a microcosm of the word. We’ve been vocabulary challenged as a product of trying to weave some of our approaches to these four systems together, which are a product of various mergers, acquisitions, etc. Market consolidation, I guess they call it.

In addition to my role at Allscripts, I’m also a practicing family physician and an EHR user, and I’m a member of the executive committee of the Electronic Health Records Association, and I’ve been asked to remind you all that I am not representing EHRA here, and that my testimony has not been vetted or voted on by our full membership. Just the disclaimer, I suppose.

I'm very enthusiastic about this opportunity, and responding to Jamie's question, you changed the start, so I'm going to try and address those rules. What must be done, what should be done, and what should not be done?

At the seat of my pants here, what must be done? Stealing from my testimony, there should be one defined owner for the harmonization and coordination of the definition and maintenance of appropriate value sets. I'll not mention an aside, although I might if I have at the time at the end about subsets, with appropriate funding allocated to this one owner.

Ideally, this one owner should have experience in this domain. Candidates would include CDC, ARC, NQF, HL-7, NLM, IHT, SDO, etc. I would foresee that an RFP might go out, and we might get somebody to own up to this and really coordinate it because I think, without central coordination, we're going to continue to have—what am I trying to say—a quilt of organizations that without all the pieces stitched together. We're going to have incomplete efforts. I think VAS is a good example, and USHIC is another good example of incomplete effort that have a little bit of overlap as well. What must be done? One owner.

Another must, how should these be distributed? They should be distributed using a publicly available repository. I had a little dialog with Floyd last night about whether this should be one thing or one thing with pointers to a distributed system. Frankly, I don't think it needs to be distributed. I think having it be one thing where all of these value sets, subsets are located and uniquely identified would be ideal. But so long as they're well organized, I think that would be acceptable.

I would imagine then EHR systems or public health systems or whatever could then subscribe to this service. There might be Web services that are available, and I might say, tell me who is a diabetic, and the value set for diabetes would be accessible. If it was updated yesterday, I would be able to subscribe to that update.

One, nineteen, and I haven't even gotten to the should. What should be done? I'll paraphrase my lengthy description here. Remember when NLM paid license SNOMED? It wasn't SNOMED CT back then. That was a great thing. It was \$32 million or so. Let's spend more of the same on other things just like it. Candidates include intelligent medical objects, intellectual property. I think it would be fantastic. It's really cool stuff.

Other candidates include HLI's language engine, which would really help the industry to weave this stuff together, so great tools, so there's great stuff. There are great tools. And I can't leave our MediCom's MEDSN, which closes some gaps in findings that I think really exist in SNOMED CT, and would help solve some of the post coordination challenges that we have in the industry. And my hero, Helen Burstin, finished early, so I'm going to be just like her, nine seconds left.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Wow. Thank you very much. I think, so for all of our panelists, thank you for keeping to the limited time for the introduction of your testimony. We're going to have plenty of time, I think, to discuss things in more detail. Dr. McKnight.

Lawrence McKnight – Siemens – Physician Consultant

Thank you. My name is Larry McKnight and, as many of you know, I'm a physician consultant. I work for Siemens, and so I come basically from the perspective of representing the inpatient solutions primarily. But my background also includes both clinical and technical aspects, including formal training and I still practice as a hospitalist.

One of the things that I find, I think, important about that clinical practice and some of the others that do medical informatics and practice medicine as well, is the disparity between what gets defined, the great work that happens in the standards organizations and the government regulations, on down to the standards food chain, we call it, the IHEs and HITSPs of the world, and then to implementations, you know, software development like we do, and on into hospitals and actually to patient care or, more typically, at least in my experience, the lack of getting to end use in patient care. And when I look at that spectrum of why that is occurring and where the roadblocks are happening, it seems to me that the best thing that the government should do is to treat the overall objectives and the projects and subprojects and value sets and implementation guides and use cases and scenarios as full projects that aren't considered complete and, therefore, accepted until they have gone through an achieved that and real world test at maybe a couple sites at least, a pilot, to make sure that you've identified all the roadblocks and the barriers because they're innumerable.

So if the government sets the objectives, and defines specific projects, then defining a use case only gets you so far. The next step is to define what are the roadblocks in getting to that higher-level objective. And, in that case, you might find some granular detail like whether or not a value set or a subset is needed. At that point, I think we should be holding whatever organizations are responsible for developing those values or subsets all the way through to a final tested solution before we mark any kind of acceptance. That's my, what the government should do.

As far as what the government should not do, I really like the phrase, rules of the road, which was kind of the title of this. And I think they should continue on that path where they set the ecosystem for the sharing of value sets, but not necessarily what the content or the specifics of value sets or subsets might be. Instead, and I'll reference my written testimony for details there, I think what's needed is a mechanism where there's full recognition upfront that there will be conflicts and overlaps created because there are many different reasons why subsets get created, many reasons why value sets might need specific constraints by different organizations. And it's not until you put all those pieces together and align them that you really find out what's working, what's not working, and why additional things might need to be included or not included.

Out of that, I think, if this group could provide some kind of guidance that allows for ownership, kind of a distributed way of maintaining those value sets by assigning owners to take care of specific problems, and then, from there allowing for a process of arbitration and maintenance, over time, including things like what happens after two years, and nobody has used the value set. Can we clear it out? Those kinds of issues, if they could provide those things, then I think we'd be in better shape. I'll leave with two seconds to go.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Great. Thank you very much, all of you. One of the things that is striking, I think, in all of your testimony is the call for defined ownership for one of the things that the government should do is to define essentially ownership. Now that, I think, leads to a question for discussion of whether the owner should be a government entity or should be a private sector entity, as some have suggested, and so what are the pros and cons of different approaches to defining that ownership? That's a question I could get reaction from our panelists and then discussion from the taskforce.

Lawrence McKnight – Siemens – Physician Consultant

I can start off. When I thought about the problem, and started thinking about all of the various different things that I personally know of as sources of value sets, I'm not sure that a single owner is possible, just because of the very nature and need. What might work and might be a specific requirement, starting out

as Floyd at the NQF, is a very different kind of problem that might need to be solved in SNOMED for what might be a particular subset or value set for some other use case. I think it needs to be distributed, centrally managed.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Centrally managed, but with ownership defined for each problem statement essentially.

Lawrence McKnight – Siemens – Physician Consultant

Exactly.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Right.

Lawrence McKnight – Siemens – Physician Consultant

Exactly. Basically just so that if there's one group that is responsible for a particular part of the piece of the puzzle, that other people know of this work, and that they are able to subscribe and have input, and that there's a process for resolution if there's need to join or if there's need to deprecate.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Okay. How do others feel about that? Chris?

Chris Brancato – Deloitte – Manager, Health Information Technology

Is it appropriate to ask a follow-on question to...? First of all, thank you for coming. Welcome to sunny Washington, D.C. Just as a followup, I represent ONC here, so I think, for the sake of getting it all on the table, we've heard in elaborate detail from all of you what the government should or must do. I'd be interested to hear your comments on what should the SDOs do, and what should industry do. I want to specifically get to Dr. Ingram's testimony on point number one. He mentions, from our perspective, it does not appear that we're short of terminologies. Moving on, we have a challenge in the clinical environment to adequately use the terms to capture the essence of the clinical encounter. So in the context of that, is that a clinician problem? What would be your suggestion to all of those?

James Ingram – Greenway Medical Technologies – CMO

I don't think it's a clinician problem. When you're using an EHR, and you're put in a situation where the only references you have as far as terminologies within the vocabulary of the EHR. In the past, we've been kind of limited by mostly vocabularies based on the billing arena, ICD-9 and CPT-4, which was grossly lacking that captures the clinical essence of patients, especially when you take in fact that later on if you're looking back from a research standpoint and trying to get some valuable clinical information out of the system, you're getting perhaps not very granular information.

To answer the question in the sense of who should have responsibility, I really look at it, as the other gentlemen have said. We're looking for a central agency that kind of manages the process, has the recommendations of maybe defining value sets and so forth. However, the reference terminology entities would be the ones that would be responsible for working off those definitions to establish the value sets and then establish their own needs in their environments, and then provide them, as I was bringing up the concept about shared value sets, where then they are added to a repository where the EHRs can extract those out in a fairly quick fashion. In other words, through a Web services type component.

In other words, readily available, so it's not something that has to go through a prolonged development period, and then slowly get into the EHRs, but really to have them available. And especially if you look at meaningful use over a period of time when you go through different stages. As you establish more value

sets, they become readily available to the end user within their vocabulary. It's not up to the clinician to try to find these things, but when they go to use the terminology, it's there, available to them quickly.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Clem, and then Floyd, and then Chris.

Clem McDonald – Regenstrief – Director & Research Scientist

...question to all of the panelists in terms of value sets and subsets. Let me first make some definitions. So there are certain things like, say, glass glaucoma score, where you've got five answers you've got to give. I mean, that's kind of a lockdown value set. And there are probably many others. But a lot of times the lines aren't clear, you know, whether you really should allow exceptions or not.

But the question about the bigger sets is, I'm wondering, do we really want to define hard edges or do we want to give people patches of stuff like this could be a good set of diagnoses, and they could add or subtract from it, because you go to specialties, you go to how many you want to put on a screen. There are all kinds of issues. The question I have is really how much work should we do on trying to define lots of containers on the bigger sets that don't have these fixed answer lists.

Jacob Reider – Allscripts – Chief Medical Informatics Officer

I'll try and respond, and maybe it's a way for me to get in my two cents about the subset topic. I am far less concerned about subsets, as you just described, Clem, with say a specialty-based subset because I think that's my problem, as a vendor, to creatively solve for my clients. I don't think it's your problem to tell me, or anybody's, or an SDO, or even a specialty society's problem. I think that's my problem to improve the usability of my software, and I think that's actually a way that we can and perhaps should compete with each other is how we make these things easy to use.

So in the sense of convenience subsets, I'd actually be on the side of saying unnecessary and shouldn't be something that we focus on in general because that's something we, individual vendors, implementers, and it's a problem we can solve. You know, if I search Google and type in JOHNNHAL, guess who I get really fast, right? And there's no subset that's been constrained. They didn't look for doctors in Boston. And they've solved the usability problem, and that's how, and they didn't need anybody to tell them about the subset I was going to search to do that. I'll be quiet and let Larry answer.

Lawrence McKnight – Siemens – Physician Consultant

The answer that I would say is that I find tremendous value and understanding explicitly what something is going to be used for. Your example of the glass glaucoma scale, I think, is really apropos. If you're passing back a LOINC code, then I'd like that LOINC code to be the right LOINC code, not just something that somebody picked because it was close. On the other hand, I think that where I see value in things like subsets, and especially for something like a problem subset, is more the frequency recording that just understanding that a particular concept is used much, much more commonly than something else can be of value to me. It is kind of a usability thing, but it can be shared, I think.

The other thing that I think is really important is the fact that not everything has to be coded. And once you get beyond a certain probability of 95% or so, who downstream really is going to need to know that with concrete certainty? And is that a candidate that could maybe be shuffled off as an exceptional case of free text? And when you get to things like problem lists, I think there's an appropriate fail over basically those kinds of issues.

Clem McDonald – Regenstrief – Director & Research Scientist

Dr. Ingram, you didn't answer.

James Ingram – Greenway Medical Technologies – CMO

I kind of concur. It really seems to me that it's left up to the vendors to come up with the mechanism of trying to find the vocabularies. We understand our clients and their needs. The challenge is trying to understand what comes from requirements like meaningful use and how to fit that into our vendor situation because, after going through the NPRM and trying to understand what our challenges are in the IFR, there are things that just, in there, I know are nice to hear from the reporting side, but are just not clinically relevant for the most part.

When I look at it, and I say, how do we capture this in our system? And why would a clinician want to capture that? You know? That's the question. There are a lot of things that are very important in the meaningful use they're going to capture, but there are some items in there that seem to be a challenge for most of us because, do our end users actually capture that on a daily basis?

Also, the frustration I think we all have is, we know it's a challenge for physicians to transition. It was for me to use an EHR. It took a while to understand it. Now I'm being forced to capture things perhaps I would not normally capture. Maybe it's better if I do capture them for quality purposes, but not everything needs to be captured. I think, with time, you can expand that up, and the EHRs will become more granular with information.

For instance, I agree, I used to think, for instance, in the HPI, it was very important to have everything codified. It isn't because there are a lot of challenges in that, and it's not that important. It is more important to have a problem list, the medications, the allergies, and things like that that we report on to be codified in a fashion that really truly means what it is when you try to get the information out to analyze it.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Thank you very much. Floyd?

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant

This is actually first a comment and then a question. The comment, what I'm hearing is, and obviously related to meaningful use and payment for systems may make sense why it is that way. It seems very physician focused. And if we're looking at care coordination and care continuum, I think we need to think about terminologies beyond the physician use. That's a comment.

What I did hear as a common theme among all of the responses was that there is a need, at least for the measurement side, to share value sets. The difference was, where should the come from? Is it a distributed method, or is it a centrally owned, managed method that can be reused? The question that comes up from the quality measure developer side is they often need to know what information is there to make sure they are getting the right patients in the denominator, the right patients in the numerator, and the right exclusions.

So the first question is, how would that work in a distributed model, unless there was a standard way to identify the same diagnosis, the same procedures across the board, and the second part is how would your customers respond to, if we don't need the exclusions, and they're not going to get to 100% performance because we won't be taking, if we did not, and I'm not saying that's what's happening, we did not take out the exclusions because those are more outside the 80% of value set requirements, how would your customers respond to that?

Jacob Reider – Allscripts – Chief Medical Informatics Officer

Can you repeat the question, please? Sorry Floyd, but all of us were reaching for our pens, and if you could be a little more succinct, that might help us.

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant

Sure. The first question was, in dealing with the distributed versus the centralized value set, do you believe you would be getting the same information if, for instance, there were four competing value sets out there, and you chose one, someone else chose another? Would you be confident that each organization using the different ones are coming up with the same patients?

Lawrence McKnight – Siemens – Physician Consultant

Actually, I can comment on that one because I was the one that mentioned the distributed. Actually, I think that is part of the management of a distributed system is to make sure that where abuses are occurring, or whether or not there are four value sets that should be harmonized, that that can be identified.

The way that that goes about does not necessarily mean that it has to be all centralized, however. It means that there needs to be a notification system where those issues can be identified. And, as soon as you try to implement that, that problem will show up. And when there is notification that there is, say, two values sets that overlap and need to be combined, then you need to get the owners of those two respective value sets together, and you need to have some kind of harmonization.

But I think that's an inevitable thing that as long as you have different organizations that have stakeholder interest, you're going to have those kinds of conflicts. And so you need a way to manage the conflicts, as they come up, and then have a mechanism to identify where they are coming up. And again, don't accept it until it's gone through at least some kind of rigorous check that, you know, kind of all the pieces and parts have been put together.

Jacob Reider – Allscripts – Chief Medical Informatics Officer

I would agree with Larry that if it were to be distributed, one would require central control like that, and now I'll try the second question, if I understand it properly. It's can we make sure that we've accounted for exclusions if the exclusions aren't explicitly expressed using known and agreed upon value sets. Is that the question?

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant

Correct.

Jacob Reider – Allscripts – Chief Medical Informatics Officer

I would answer no, and the value sets would need to be explicitly expressed in those exclusions. There would be no other way for us to do it because that's how we would know upfront. So if I were to say, consumer a value set in my system, then I would understand, so I would consume a quality measure. Of course, I'd be consuming that in the HL-7 DSTU standard health quality measures format XML. Right, Floyd? So I would be consuming it in that way, and those value sets would represent the exclusions. Then I would know up front, well, people will purple toenails are excluded from this quality measure. Therefore, I need to capture what color their toenails are up front, right? That's....

James Ingram – Greenway Medical Technologies – CMO

I'm wondering if what you're saying is you could use a statistical method instead? You know, instead of saying you had 100%, but you did exclusions. You say, well, on average, it can be 80%. Then that would save all the work because the exclusions create this huge list of things you have to say. Am I capturing it right?

Clem McDonald – Regenstrief – Director & Research Scientist

Actually, that's a great answer to my question, and I was asking....

James Ingram – Greenway Medical Technologies – CMO

I'm sorry....

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant

No, no, the reason I was asking them is how would their customers respond to that, and I would agree with you, Clem.

Clem McDonald – Regenstrief – Director & Research Scientist

What I want to know, though, is upfront, if I'm going to need to capture data that I don't have, and that's where, so what I'm doing is I'm pushing the envelope, and I'm saying to the measure developer, please tell me what you're going to need to know. You heard Floyd say it. They're going to say, please tell me what you have, right, because that's how quality measures were developed back in the bad old days before 2010, right? They would go into the medical records room, and they'd look around for what data was there. Tell us what data you need, and we'll make sure we get it.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Sorry. Go ahead.

Lawrence McKnight – Siemens – Physician Consultant

I would say that in many cases the devil may be in the details on that, and I'm not sure that I'm qualified to answer because it's really the hospitals that would be most affected by that if they have some metric and maybe their percentage of exclusions is higher or lower for some reason because of demographics that could cause some problem. On the other hand, they're the ones that are going through the pain of trying to determine things on paper, and so they might very much appreciate it. But I think it would be the end customers, you know, the hospitals and health providers.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

If I could just ask a follow up on the same topic before we go to Chris Chute, and that is, it's been noted that a lot of the exclusionary criteria have very long tails, essentially very infrequently used terms that may be some of the items that it sounded almost like a complaint that these are things that aren't typically captured. And so, is there – I guess a different version of this question is, how onerous is it when those exclusionary criteria would be included in these value sets as the request for what to be captured, but these are things that aren't normally captured in that method? Is that unduly onerous from your viewpoint?

Lawrence McKnight – Siemens – Physician Consultant

I think it's a real challenge because there's very little part of documentation of a patient's visit that we think in negation that we don't, and we exclude that. Traditionally, years ago, in the written world, we would say something to that effect. In the EHRs, it's not as prominent.

And to use another environment, such as clinical research and feasibility studies where it's often put into exclusionary criteria, it's very challenging to look in an EHR and find that you've excluded something because you don't purposely set it up to set for exclusions. So it is a challenge when value sets are set up with a lot of exclusion criteria.

Jacob Reider – Allscripts – Chief Medical Informatics Officer

I would agree that it's onerous. In fact, that's, on some level, my point because if the tail is very long, and it becomes onerous for the measure developer to develop it, then there will be a disincentive for them to create such a long tail. And I'm really serious about that, so not trying to play games and say, hey, you do all the hard work. But if they saw how much hard work it was, which of the 2,700 SNOMED CT codes did you mean there, then it exposes this problem that has, I think, heretofore been hidden.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Okay. One more follow-up on this, and then....

Jacob Reider – Allscripts – Chief Medical Informatics Officer

The question I think then would come back to is, could one, could you guys want to suggest a strategy where you'd pick out those things would demographically, statistically involve, like inner city or whatever might change their scoring, and then maybe come up with some estimates, and then do it on a statistical basis, so you set the threshold lower to accommodate all that long tail of exclusions, but you still can accommodate the big differences? Would that be helpful, or could you do that, Floyd?

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant

I guess that's another expert panel we'll have to have.

Lawrence McKnight – Siemens – Physician Consultant

My response as a vendor would be, I would look to Floyd and the measure developers for those things. We create tools. I think that's a content question, but if given that content, we could certainly process it.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Thank you very much. Now, finally, we will go to Chris Chute's question.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards

Thank you very much. I want to go back to the centralized, decentralized thing. Being a centralist kind of guy, that's the right answer, but nevertheless, I can see advantages and disadvantages to both approaches, clearly. One could quibble that a centralized approach would be nonresponsive to user needs, to usability, to all kinds of parameters. Yet, the great paranoia of many of us of a decentralized system is interoperability goes out the window.

Instead of trying to resolve that question, the usual response under these kinds of circumstances, if both answers are potentially right, is I have a modest question for you, and that is, can you articulate the principles and best practices that, in your minds, from the perspective of vendors and representing that user community, should be or should guide the maintenance, delivery, and management of vocabulary value sets and content?

Lawrence McKnight – Siemens – Physician Consultant

I can take an early stab at this. In a lot of our hospitals, we might have upwards towards 100, 125 different systems that are all talking to each other. And there's a lot of complexity that arises when those kinds of things happen. And, under ideal circumstances, you would replace that whole thing with a big, single system, and it would solve all that problem. And yet, very few, if anybody, can really achieve that goal. Maybe Mayo has, but the last time I was there, they still had several systems too.

Because of that problem, you develop strategies around trying to maintain a really complex system that don't depend on a centralization. For example, you do unit testing and extensive regression testing before you replace any little module. And that goes through a cycle if you can isolate within a unit and roll

out in a small phase so that you understand what the problems are before you try to make it work, then that's helpful to insure that you've got the right thing in place before you go forward.

For the things that need to get defined, if they're just between two small parts of the system, then that should be free, from my perspective, to float on its own, as long as it's not affecting anybody else. But as soon as you get to the higher level constructs that need alignment between various different parties, then you need to be progressively more and more careful. To me, that means it has to be tested for those things.

James Ingram – Greenway Medical Technologies – CMO

I think that's one of the challenges that ambulatory practices have versus hospital based practices that, for the most part, physician offices don't have the ability to do testing. They're expecting it to be done prior to using it at the point of care. But I still think that the distributed model works and, at least in my mindset, an idea that where there's a central management of value sets, either entities such as your agency, with Floyd's agency, would pass information to that for kind of a water test of whether or not that's appropriate, it fits into the constraints of the definition, and then it's allowed then to become part of the public domain where we can then, as EHRs, consume that. I think that obviously has value from different perspectives to produce value sets, but to have to have a consistency of definition of what they are, and have someone review those, and to make sure they're consistent across the whole environment, whether they go to a hospital based system or an ambulatory based system.

Jacob Reider – Allscripts – Chief Medical Informatics Officer

What if we think of this as open source? We look at the open source community. How do they manage things? Generally, there's a central place, but it doesn't always have to be that central place. There's distributed development. There's usually an owner or a herd of owners who have rights and responsibilities to keep that central core pristine. And when people participate adequately and get the right level of responsibility, they're anointed, and they can participate too. So I think that actually might be a very good model.

Often these kinds of projects are funded, so back to what we, I think, all said initially, clear ownership, right? We didn't say clearly own all of the code and all of where the people are doing the work. We said clear ownership of the process. So I think, back to the musts and should. I had, in the category of must, establish clear ownership of this.

And so, in an early draft of my testimony, I had distributed. And in the last draft, I had centralized, so you can see that I'm on the fence about this too, and I think it doesn't matter as long as there's clarity of process. And that needs to be centralized.

Andy Wiesenthal – Kaiser Permanente – Exec. Dir. CIS

Jamie?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Yes.

Andy Wiesenthal – Kaiser Permanente – Exec. Dir. CIS

This is Andy Wiesenthal. I think the synthesis of both of the most recent comments is really the path that seems most useful. I'm an infectious disease doctor, and I always think about antibody molecules. This is probably either boring or too arcane for everybody else on the call, but they have a core that doesn't vary chemically. And then, at the place where their action occurs, where they're actually working, there's the capacity for those molecules to change and innovate to meet the challenge of new invaders.

And so, having some defined core, however we choose to govern it, whether it's with open source techniques or by some other central technique that is clear, understood by everyone, and has structural rules that no one is allowed to violate without a lot of debate and discussion to change, then, at the very edges where innovation has to take place, the possibility for local individuals even to extend it, play with it, and try new things is probably the most appealing way to tackle this problem, and it really represents a hybrid of both central control and distributed management.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Thanks, Andy. Floyd?

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant

Not to make this an infectious disease response, but as another infectious disease physician, I actually like that model, as he described. I think what I'm hearing though is some structure around how things are managed centrally. What concerns me a bit is there are a couple of use cases around secondary use, one of which is quality, one of which is clinical research, another is public health and public health reporting that have enough similarities that I think there has to be some centralization for some of that, even though – and running around, using similar governance requirements for other use as well.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Okay. Thank you. Stan, a question?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

Well, some comments and, I guess, a request for a response. Listening, just a few observations: One would be that we'd probably need some rules or at least some discussion about how do we use this operationally. When can we have exceptions and not have exceptions and that sort of stuff?

Another thing is, I think, as we have these discussions, we talk about value sets, and it's well defined. But it's a spectrum of things, and Clem kind of pointed to that. You have these large things that have some fuzzy boundaries around things like problem lists or signs and symptoms or past medical history. And then you have some things that are fairly large, but most people would say it's pretty important to code them, like drugs and allergic substances.

Then you have lots of these small sets that are like the answers that you can give for Apgar scores. And so, as we think about solutions, I think we need to think about that spectrum, not always just think about problem lists, and somebody else is thinking about Apgar scores. And you argue about how we maintain and do those, because I think there might be quite a different approach to the big ones versus the little tiny. So I think it'd help to kind of keep that in perspective.

Then to kind of drill down on what people have said about owners. You know how to say this. I think the owners have to be the people who have the money or the authority to dictate the sharing or exchange of data. So in our context, I think that it could be public health departments for sharing public data. It could be the CDC at the national level for that same purpose. I think it's CMS for when this data is being used for quality or to support understanding clinical care. It could be the National Quality Forum if we're participating in quality activities. It's the FDA if we're trying to do reporting of drug. You know, I mean, I think, ultimately, those have to be the owners of the thing.

And though certainly LOINC, SNOMED, and IHT SDO have a role, they don't have the fiduciary responsibility for those things. They should be essentially working the staff to support those things, but ultimately the responsibility, I think, has to resolve to the people who have either legal regulatory

responsibility for the sharing of the data. What that says, though, is having them – that comes to the distribute versus central. Worst case though is that if those people had responsibility and then the FDA were describing value sets one way, and NCI was doing it yet a different way, and that would be a nightmare. So what we need is that central authority that is standardizing distribution and technology and the representation of the things. And then that makes sense. Distinguish owner from sort of distributor. There has to be somebody that sort of worries about the infrastructure and how we do the sharing, and distinguish that role from who has responsibility for the content, if you will.

And then you know my constant whine, which is, none of these things make any sense unless you tie them back to a message or a structure that defines the exact, you know, a use case of, you know, we're exchanging this data so that we can report reportable diseases to the public health department, and we're going to use this HL-7 message to do it. Or this is for a prescription from a provider to a pharmacy, and now we know we're going to use NCPDP Script there, and we absolutely have to tie these things back to the exact use case. That's part, I think, just remembering that, as we talk about mechanisms for distribution. Just thoughts and invite response.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Okay. Let me ask for responses, I guess, to both of Stan's main points from the panelists, one that ownership should derive from both authority and funding, and then the other – well, let's start with that one.

James Ingram – Greenway Medical Technologies – CMO

I agree. I think that's what we're looking for is, at least in my mindset, is that I'm looking for some continuity. I mean, it's no different to use a car analogy. There are a lot of different tire manufacturers, and what they will all do is abide by the standard. And so you can interchange those, and that's a simplified way of looking, but basically what I think I'm expecting is some central organization that can fund that, can direct it, can provide the insight to what we're trying to expect out of this in a national mindset because we are moving towards a national approach to healthcare from the terminology world, and that's what I would expect to see.

Lawrence McKnight – Siemens – Physician Consultant

I would also agree with almost everything that Stan said. The only maybe point on it is about distribution. I really agree that distribution and content maintenance are two separate things. And it would be nice, if you're talking about a centralization of repository, that's something that can be standardized and probably brought together, just as a central place to share. When I say that I think that ownership and distributed kind of ownership, I'm really referring to the content maintenance of these very granular, little things where different people have different expertise and different needs. And as long as there are rules of the road, and a groundwork, you know, a framework for that, then I think that's where I would stand.

James Ingram – Greenway Medical Technologies – CMO

I would bring up one thing again, as I mentioned earlier in my testimony, is still IHE has got a profile in insuring data sets, and I know it's early on in that phase, but it seems to be a pretty reasonable approach to that.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Okay. Thank you. Clem, did you have a follow-up on this?

Clem McDonald – Regenstrief – Director & Research Scientist

Well, it's kind of a comment on Stan's, well, kind of everybody's ... sort of ... maybe on my life. I started out when there was a code set that had 1,000 codes in it. It came out of AMAI, and that was supposed to

be all we needed. And I'm continuously sort of wondrous at how much I keep getting surprised, after being in this field ... how much more there is. And there's almost like there are not enough words, and there aren't enough concepts. And we use context to reuse the words in context and useful ways. When we make these projections about how we're going to do all this all together once, and we haven't gotten there yet, it scares the heck out of me, I guess, just a little bit.

Jacob Reider – Allscripts – Chief Medical Informatics Officer

I'll echo that, and maybe respond to Stan and maybe even Floyd a little bit. It's got to be simpler than it is. And I think, when we have a distributed interest in expanding the number of letters in the alphabet, there does need to be a central owner of that process, and that's kind of what I was talking about.

Jamie, you said derived from, and I think that was key because I wouldn't necessarily expect CMS to own, but I could look to an NQF to own on behalf of CMS, and I think that their processes, not to pick on anyone in the room, their processes might be better than those at CMS, and they might be more agile. And, in fact, they might be able to make sure that there are still only 26 letters in the alphabet. I do fear that we're going to keep – because with all the different perspectives, there are going to be different ways to look at things.

If you say, hey, you know what? The CDC had that same idea that New York State Health Department had three weeks ago. And there's got to be somebody to say, hey, guys. Why don't you talk to each other? You're actually saying the same thing.

Lawrence McKnight – Siemens – Physician Consultant

Yes. One of the challenges, I think, and our company has come across in the last probably year to two years, was the emphasis on quality reporting as not only are there governmental agencies out there, but there are some private entities out there that want to profess quality experience, and requesting from EHRs to have these quality measures within our environment. And they're not really holding themselves to any particular standards, and it's very difficult to try to accommodate that because sometimes what happens is they put pay for performance behind their world.

And so a lot of the clinicians say, gee. I want to get this pay for performance from this entity. Can we do it through the EHR? When we look at those particular quality measures that we need to respond to, we find them very difficult to incorporate those in our product. This is where I'm talking about saying, sure. We can do it if you abide by certain standards, and point back to a central agency.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Great. Thank you. Betsy?

Betsy Humphreys – National Library of Medicine – Deputy Director

To ask maybe a mundane question here, a little off the topic of these others, but maybe not, where you're sitting right now, you have to deal with, even if you're only doing administrative, you have to deal with multiple code sets, and you have to deal with the classic, different distribution schedule issue between when people are required to use CPT versus when they're required to use the next year's version of ICD-9, 10, CM.

And then we all know that a schedule like that is not workable for medications. You obviously need to have, if you're going to standardize medications, you have to have new medications at the time they're approved for use in the United States or wherever else your products are sold. And then you have the issue of the tests, like obviously a new test can come in or the lab you use can switch to a different method of measuring the same thing.

My question is, should we just not worry about this problem in terms of something like SNOMED, or should we align it if we ever could with something else? I'm not saying we can. You understand. But have you all done whatever you have to do now so that if we were able to wave a wand and say there won't be this different distribution schedule for CPT and ICD-9 CM, you'd say, oh, for goodness sake. Leave it the way it is because we're already dealing with it. What about the scheduling issue? Is it a big problem?

Lawrence McKnight – Siemens – Physician Consultant

I can say, within our product, we do have a lot of alignment issues that have to happen, in part because we have separate products that need to talk to each other, you know, and there is definitely issues that arise out of the alignment of content that they need to work and be using the same set of assumptions, essentially the same value set, in the case of medications and allergies in particular. But it is a process that I think is manageable and probably almost necessarily, at least in the hospital space, has to be managed through the vendors. Under ideal circumstances, I guess, yes, if there was an alignment point, but again, I think there are just too many sources where this information is coming from that it would never, you would never get agreement on, you always must be at this month or this day because everybody has different priorities there.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

If I could just perhaps re-ask the question, also from the perspective of your customers, the users of the EHR, if all updates, I mean, just hypothetically were published on the second Tuesday of the month for everything, then how much of a difference would that make for them?

James Ingram – Greenway Medical Technologies – CMO

To me, it's how your system handles those. In our particular system, which we handle it through a central way of distribution. All our practices are connected through us 24/7. So when it comes time to update an ICD, CPT, whatever you want to update, whether it's monthly or semiannually, or annually, we can do that in a very simple process.

But not all EHRs handle it that way, and that's the challenge. Some require, you know, onsite loading of an upgrade. Our upgrade is done almost instantaneously, so we've kind of prepared ourselves for that type of process. So it's a little bit easier for us, but I would say that that's not consistent across the whole spectrum of the EHR. So it is a challenge for upgrades.

Jacob Reider – Allscripts – Chief Medical Informatics Officer

I would agree that the ability of EHR vendors to consume what we call at our company JRJITI, just right just in time information, is variable. So you've got your CD-ROM mailing at some places, and some practices just physically aren't connected. So we can't expect that there's that, but I think there are two separate issues. And I think that the availability of the information is one. And my answer would be generally consistent with both of the other ones, which is, get it out there. And don't worry too much about coordinating the schedules.

A, deliver SAP; B, make sure we have good versioning so that we know which one that we're using. That was, I think, something everybody agrees on. And then, C, where policy dictates, we need to be clear about what version is expected with what timing. And so we've all seen the scenario where client X, Y, or Z declines to accept the update for whatever reason. They think it'll infect their system, and they're running on the six-year-old version of whatever it is they're using. And then when they can't get paid is when they finally decide that they're going to upgrade, and that's their choice. Right? But there should

be policy that defines when they do that and consequences like not being paid would be a good one. It would outline what would happen if not. So I think we answered the question.

Lawrence McKnight – Siemens – Physician Consultant

I would agree with all of that. The only other thing that I would maybe say is that there should be an assumption that when a value set or subset or terminology is distributed that there's still a significant amount of massaging that needs to happen on that content in order to get it into a product. There are hundreds of different variations of how long the values can be in this system or that system because they assigned 32 bits or 32 characters here and 64 over there, and so for all of those names, you've got to assign 32 character names. It just goes on and on. International characters, you know, foreign languages, so there's a lot of massaging that needs to occur, and so even if they were aligned, it would still have to go through our processes.

Jacob Reider – Allscripts – Chief Medical Informatics Officer

I just have to comment that having seen what happens when you abbreviate things and what that actually looks like to a clinician or anybody administrative, I think that actually that practice is the enemy of interoperability.

Betsy Humphreys – National Library of Medicine – Deputy Director

...patient safety as well.

Jacob Reider – Allscripts – Chief Medical Informatics Officer

Yes.

James Ingram – Greenway Medical Technologies – CMO

Even for interoperability, I think it flips up an issue of just usability.

Betsy Humphreys – National Library of Medicine – Deputy Director

Yes. I think that, well, of course, we all have our horror stories of, you can only – you have to say it in 32 characters. But, unfortunately, it's not distinct in 32 characters.

James Ingram – Greenway Medical Technologies – CMO

Right.

Betsy Humphreys – National Library of Medicine – Deputy Director

So then you have 52 different ways of under-specifying what you mean because everybody has jammed it into 32 characters using a different approach to specifying the 32 characters. Let's hope in the next generation of everyone's systems, they become a little bit more flexible.

James Ingram – Greenway Medical Technologies – CMO

Yes.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Okay. Thank you. I think Floyd was next, and then Chris.

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant

All right. Actually, I wanted to go back to a statement that Larry made, and that was about looking at a distributed model and having the value sets tested. I think what I heard you say was testing in a couple real environments, but perhaps also some testing against a test deck of patients or something like that, so I wanted to hear a little bit more about what you meant by testing.

Lawrence McKnight – Siemens – Physician Consultant

Ultimately, what I mean by testing is, like you said the first time, live patient data, multiple sites. The reason for that is because, in rolling out a particular concept, you're talking about communication between two different people, and if it's miscommunication, for whatever reason, that the value sets are inappropriately defined, then you really may not recognize that until you get to the final stages. And it would be better if you did that in a smaller environment, and then progressively roll it out.

As far as the levels of testing in between, you know, could you do a test harness in advance or something like a connect-a-thon test? I think all those things are good. But it is a progressive state, and the testing does not just testing of the system. It's testing of the specification itself, which corrects the specification for all of the things. It's often where you also find where these misalignments are because you find that, hey, how come you didn't use this coding system that I'm already using for this other quality metric, what I'm doing over here? And those things will become readily apparent when you try to put it into real systems.

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant

Can I just follow up? So I understand, but I guess my question was referring to terminologies recommended by standards committee or potentially in the interim final rule or the next final rule. And in the near term, if we were testing a specific value set against an existing system where that terminology isn't there yet, what would you recommend for an interim? If we think of the ideal when everything is implemented, it makes sense. I'm thinking about, what would you recommend for an interim?

Lawrence McKnight – Siemens – Physician Consultant

Such as specifically the recommendation of SNOMED for problems?

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant

You could use that as a good example.

Lawrence McKnight – Siemens – Physician Consultant

And people ... in their old coded systems? I think putting the measure out there as, this is something that we want to try, and this is what we think ought to be done is completely valid at this stage, and we should be doing that in large volume in order to get progress. We are doing that in large volume.

On the other hand, that doesn't mean that it is ready at 4,000 hospitals and how many physician practices are there? A lot of physician practices. You know, it may not be appropriate at that stage yet, so you need to go through a progressive implementation phase, and understand that it will take time, and that there may need to be changes before it's rolled out to broader certification kinds of requirements.

James Ingram – Greenway Medical Technologies – CMO

To me, one example that became very obvious to me is when we started looking at doing flow sheets and automatically populating flow sheets with electronic lab information. We deal with a lot of different practices connecting a lot of different laboratories, and probably you're going to go along with this, Larry, is that hospitals are notorious for not connecting to LOINC ... labs, and so most of our interfaces with any hospital system, even though we're an ambulatory thing, a lot of practices send labs to the local hospital. They are not LOINC coded pretty much across the board, and they don't intend to be because there are no requirements for them to be that way that I'm aware of.

As a result, we get information back that's not LOINC coded. We handle that in our system, as I explained in the testimony, in a different fashion, putting the work on the site to do the mapping. But one

of the requirements are, if you're going to use LOINC observation codes for lab results, then we've got to have some piece into it that labs need to comply with this. Some of the national labs do it, but not all sites do it. A lot of those national labs have consumed smaller labs, and they may be administratively connected, but they aren't handling the results in the same fashion.

Jacob Reider – Allscripts – Chief Medical Informatics Officer

Do we dare open that Pandora's box? I'll just say, hear, hear to that one.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

I think that particular one is out of scope for this session.

Jacob Reider – Allscripts – Chief Medical Informatics Officer

Exactly.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

But point noted. Clem, do you have a follow-up on that?

Clem McDonald – Regenstrief – Director & Research Scientist

I mean, if they'd paid a penny a result the lab delivers, it'd be more work, I think, than all this other stuff because, you know, for a properly messaged result, we need ... so hear, hear too.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Okay. Thank you. Chris, I believe your question was next.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards

Thank you. I, unfortunately, am getting old enough that I've heard some of this before. And, in particular, I want to draw all our attention to the 1996 Computerized Patient Record Institute Summit on health information standards where it was articulated and, sadly, many of the people in this room were that. In fact, I think Betsy actually crafted this final language. But in 1996, it was determined by the collective wisdom of our nation that we should select or create an entity serving the public interest to coordinate healthcare terminology, and we went on. So I don't mean to be cynical.

Betsy Humphreys – National Library of Medicine – Deputy Director

I didn't craft that. If they had listened to me, they would have recommended that somebody within HHS be given the responsibility. Sorry.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards

There was a lot of debate whether it should be public or private, and I think the final recommendation was....

Betsy Humphreys – National Library of Medicine – Deputy Director

I was on the public side of that....

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards

...unspecified. It could be either. So I don't mean to dwell on history or be completely cynical, but what I do hope to elicit from you is, so why hasn't this happened? And from your point of view, what are the barriers to doing what seems to be collectively a kind of agreed upon, smart thing to do? And, more pertinently, what do you think this committee, this process, this opportunity can propose or suggest to finally get over that barrier? A simple question.

Jacob Reider – Allscripts – Chief Medical Informatics Officer

I think it's easy. But I agree with Jamie. It's out of scope, probably of ONC even. But to Clem's point, it's all about payment, right? So why do people use ICD-9 codes? I put this in my testimony? What's adopted? What has worked and has been adopted? Well, it's very clear that what's been adopted has been what is compensated. And so, let's tie compensation to doing the right thing, and people will follow. It's very clear to me.

So people don't share LOINC, right? It's a big problem. We are all chasing our tails over this problem. And if we can incentivize labs, and if it's a penny a lab, I don't care. But right now, they can get away with CPT, right? So they'll bill for CPT, and then what do I get? Gobbledygook.

Lawrence McKnight – Siemens – Physician Consultant

Agree. I mean, I think it absolutely is tied to whatever incentive you give, and the incentives for those hospital labs to switch over right now is very low because they have something that kind of works for themselves, and it's a big, complicated mess, and they don't really want to touch it if they don't have to.

James Ingram – Greenway Medical Technologies – CMO

From the lab standpoint, they have automated systems for the most part. It puts out a report. They just pass that on to the offices. So it goes really back, not necessarily to the hospital, but goes into the automated lab equipment that don't produce a LOINC result to that. If they did, it would be fairly straightforward. The hospitals would probably send it out. So I'm not sure. A penny a lab may motivate somebody, but it really goes all the way back to the actual machine manufacturer to put that type of reference into the reporting structure.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

I would argue, that's something that is potentially within the scope of recommendations we could make here to FDA, which regulates exactly those devices.

James Ingram – Greenway Medical Technologies – CMO

Absolutely.

Jacob Reider – Allscripts – Chief Medical Informatics Officer

Actually, that is probably coming. I don't know....

W

Recommend it anyway.

Jacob Reider – Allscripts – Chief Medical Informatics Officer

Yes, recommend it anyway. Make sure it comes. There are actually thoughts and plans along that line in the device division.

James Ingram – Greenway Medical Technologies – CMO

Also, maybe this is not even the right forum to do it, but I know, as a surgeon, one of the challenges for like in e-prescribing, and part of your requirements in meaningful use is be using e-prescribing. Well, as a surgeon, right now you cannot do controlled substances, a huge hit for anybody that uses controlled substances. Even to the point where, say, for a neurologist doing sleep medicine, can't even prescribe sleep aids through e-prescribing. So we can't do anything about it. I suspected that we would have had something done by now, but it's a big delay on it.

And so what we find is that we only can go so far as a vendor, and then we're stuck. So we try to accommodate as best we can, but we're really looking for some guidance out there saying, here. We're going to take a national approach to electronic health records, and FDA, you've got to come onboard with this. You've got to move forward with this. Labs, you've got to move forward with this.

Lawrence McKnight – Siemens – Physician Consultant

And I would suggest that it's not just the FDA. Also, CMS has a huge role in this, in particular, around the way that physicians build their daily note. You know, I get paid by the bullet, and I can pretty much guarantee that most EHRs that do physician billing are going to know what those bullets are. But they don't pay for a standardized problem list.

Jacob Reider – Allscripts – Chief Medical Informatics Officer

I was a general internist. I couldn't help that.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

That's good. Okay. Other questions? Do any of our taskforce members on the phone have other questions for this panel? Okay. Any other questions for this portion of our discussion? Clem?

Clem McDonald – Regenstrief – Director & Research Scientist

...wrong thing, and just probably I shouldn't launch it, but do you have complaints about the CLIA in terms of the results reporting, or are there any things you'd like to change there?

James Ingram – Greenway Medical Technologies – CMO

From my perspective, not really.

Jacob Reider – Allscripts – Chief Medical Informatics Officer

I would say that's another opportunity, right, along the same lines as the one that you mentioned. If we can incentivize providers to record lab values that were obtained in the practice in a meaningful way, potentially using LOINC codes, and that might even cause us, right, so we need to make it very easy for our clients to capture those things and attach them with LOINC codes. Maybe I was swinging at your softball there.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Okay. Well, I want to thank you all very much for coming in here today, and truly appreciate it. I hope this was as valuable for you as it is for us. We started a few minutes early. We're going to end a few minutes early on this panel. We're going to take our lunch break now, and we will come back at 1:00 eastern.

(Participants Break)

Betsy Humphreys – National Library of Medicine – Deputy Director

All right. We're getting ready for our next set of panelists. These are people who are involved in providing terminology services. I like looking across the table at this panel. I recognize many friends. I'm also, in a very parochial way, happy that the National Library of Medicine contributed to the careers and work of a number of the people there as well. And I think that you'll all agree that we spent the taxpayers' money very wisely when we supported them. Why don't we just go across from left to right, and we'll start with Lee Min.

Lee Min Lau – 3M Health Information Systems – Medical Informatics

So does that mean we can blame you? All right. Hello. I'm Lee Min Lau, and as you guys probably know very well, when I get excited, I talk fast, and I have an accent, so just feel free to say, "Slow down." I'm from 3M, and thank you very much for inviting me here today. Also, thank you, Judy, for doing such a great job of organizing all the written testimonies because I had a great time reading them, and it certainly made the four hour delay coming here just pass by in a flash.

So I'm not going to go through all the stuff that you guys hopefully have also read and probably get a lot more out of it than I would, but I can already see that a spectrum of expectations, a spectrum of understanding, a spectrum of recommendations as to how we should tackle this problem. I think it's fantastic of this taskforce to go right into the one problem that really showcases the complexity and the importance of terminology and data because you guys are zooming into what's on the surface, looks like a simple problem. After all, you're zooming into subsets and value sets. But that really shows up all the issues we are going to see for terminology as a whole and standards and data as a whole. So I applaud you for that, but I don't envy you, your jobs.

Now you ask us to recommend what the government's role would be. I would think that right now to even decide what your role should be is the key because there are just so many variations that you can play, and even from the written testimony, you see this whole spectrum. You've got people on one end saying one centralized source, one centralized ownership, and I hope that also means management ... and all of that, to here's a set of rules, and everybody who follow those rules should submit and have value sets and subsets.

Even that decision and then going through every single step that results from that decision is key, and I don't mean just on a very high level basis. I mean actually taking something, using as an example, and going through every step because you are going to find a lot of unintentional and potential problems that will result from your decisions. And I call them unintentional consequences.

One example I'll use will be mapping. I mean, right now, you're hearing a lot of people say mapping is bad. You have all these problems. But that would be like me blaming the car when I slip down the driveway and telling my husband, "See, I need a new car," when it was my decision not to shovel the driveway, all the snow that caused that problem.

Because it is not the methodology, is not even terminologies, it is how they are implemented that's going to be the problem. So the unintended consequences is, for instance, when you say let's use standards. What you are going to see out there is people saying, at all costs, regardless of how correctly I do it; I'm going to use standards.

So we're having a situation where two organizations exchanging data actually say something like we must have LOINC. So I don't care if my results doesn't exist in LOINC. I'm just going to find what I call a best fit, and stick it through, send it to you, and you do the same thing. It doesn't matter if you don't have that exact result. Just fit it to a best fit. And, before you know it, yes, we are all using standards, but the data itself is not accurate. So those are the kinds of unintentional consequences I'm talking about, and that the government needs to think through.

To quickly summarize the issues without repeating what I wrote in the written testimony and others, is that there is this need for simplification, and we understand that. We want things simple. We want things easy to use. But complexity doesn't go away. It's going to be there, and it has to be dealt with, so either we upfront say we recognize it. We decide that we are going to ask for a minimum level of education, and everyone has just got to learn that, and/or we say there are going to be people who have to focus on that and deal with that, and the rest of us are just users.

I'm not saying that because I'm a terminology provider, and I want a job. My previous job was chief of outcomes research and quality assurance, and very quickly find that no good data, no good outcomes research. So I went to the dark side, joined terminology, tried to fix the problem, and 15 years later, I still haven't been able to get to the outcomes research world. So if you want to think about it, I was a user, and now I'm a dealer, and I'm still an addict because I still really care about data and terminology, and I'm really excited that through this meaningful use and through all of this attention, that maybe we'll start to solve the problem, and I can return to my first love, which is data. Second love is husband.

So it is not a temporary problem that will go away. That's another thing. People want to think terminology is a one-time problem. You solve it. Now go away, and let all of us play with the results. Not happening. And the government can play a role in really promoting that thinking and say let's just manage it forever.

Betsy Humphreys – National Library of Medicine – Deputy Director

All right. Rob McClure, next.

Robert McClure – Apelon – VP & CMO

Thank you. I'm actually going to read here just to keep myself on track. Otherwise we'll go all over the place. So my name is Rob McClure. I previously practiced internal medicine and pediatrics, and I'm currently the chief medical officer at Apelon.

A little bit about Apelon, Apelon has been in the healthcare terminology space for over 12 years and is focused on delivering terminology, what we call terminology asset management professional services to a wide range of private and public clients. The most recently and I think illustratively with the HITSP quality tiger team, in collaboration with the National Quality Forum and the VA.

We'd like to thank the committee for the opportunity to provide input on, I think, this very important deliberation on subsets and value sets, and provide feedback to the questions. You've received our submitted comments, and I'd like to highlight a couple of things out of that, plus some other interesting information.

First off, we believe that the health information technology implementers do not want to create value sets—you heard that this morning—on their own, and that they will use externally developed value sets if and only if they're confident that the content is vetted by reputable bodies, and the content can be integrated into appropriate workflows in their environment. I think those are the critical issues.

Value sets for us, value sets represent sets of concepts focused on data capture and information sharing. The organizations that are responsible for information to be shared must be responsible for defining the content of the requisite value sets, and this should be done via an open and transparent process that results in well-documented content that's easy to obtain and integrate. I'd like to highlight that for key areas, creating a unified model with value sets, such as what's been described as detailed clinical models or archetypes is a very important component of this. They are very closely tied together. I think Chris talked about this, and others have.

Now we see subsets as something more general than value sets. And not necessarily tied to any particular information structure or use case. So I'm making a very clear statement about a particular way of thinking about subsets. And so as that subset serve as a guidepost that value set developers can make use of. So as an example, I could imagine a U.S. regulatory body could define a subset of reportable clinical diseases drawn from SNOMED CT, and then an implementer would use that to define a specific value set for reporting resistant bacterial infections occurring in intensive care units.

We also believe that developing value sets is hard, but achievable activity that would be much easier for organizations responsible for defining this content if they had common tools and the ability to discover value sets that are already available for reuse. Given the expectation that multiple organizations will be responsible for truly appropriate value sets, there needs to be an infrastructure—and we've heard about this already today—that makes it easy to produce consistent and searchable content with a common structure that is maintainable. This infrastructure needs to provide both tooling and guidance, and while we believe that, over time, there could and perhaps should be multiple loci for this to occur, we need to start with at least one that's focused on the needs of the U.S. requirements, most notably those in support of meaningful use.

I'd like to echo what others have said about emphasizing that we do not need to encode everything. This is one of my mantras that we need to exchange lots of text. That's one of the things that's valuable about electronic health records, but it's about eyeball-to-eyeball interoperability between clinicians, and that we focus on encoding those things that we know we need to compute based on, and not necessarily other things, and that that changes over the course of time, so we have to support for that.

Finally, we believe that the most effective role for the government in this area would be to work with both SDOs and organizations, such as the National Quality Forum, that are focused on improving clinical care and meaningful use to develop the infrastructure needed to create, evaluate, deploy, and maintain value sets, and to implement this in the very near term by standing up at least one value set registry and repository. We'd like to see that this repository be taken on with an understanding of the commitment that it takes to do this, and to utilize the good work that's been done by existing organizations already swimming in these waters, organizations such as the ARC's USHIK, the National Cancer Institute's collaboration, well, that's the new collaboration with CDISC for CDISC SHARE, the CDC's PHIN-VADs, and the National Quality Forum's initial work on quality measures.

We need to learn from this. I'm not saying we pick one, but we need to make sure that we build upon that, and we get something going. And we use that as a demonstration that this can be done. And we put together the tools to make it reproducible, as necessary, in other places. For example, it's important that the quality forum do quality stuff, and the public health forums do public health stuff.

With that, I've completed my prepared oral comments, and you've got my written comments. Thanks.

Betsy Humphreys – National Library of Medicine – Deputy Director

Thanks very much, Rob. Brian?

Brian Levy – Health Language – SVP & CMO

Hello. Thanks. Just a little bit about my background here, I'm the chief medical officer of a healthcare terminology services company, Health Language. I also serve as the cochair of the CCHIT Advanced Interoperability Workgroup, and I also manage to squeeze in some hospitalist work during my increasingly limited amount of free time these days.

I wanted to focus a little bit on more of what we call the convenience subsets, and that is, spend a little bit of time on the use of these subsets that are going to be particularly relevant to support kind of the structured and unstructured data entry requirements through the electronic medical records. Not spend so much time on kind of the value sets, although I think some of the same issues certainly apply.

Just kind of a general, practical points, I do like the idea of having some kind of nationally defined, larger, useful, convenience subsets, such as the National Library of Medicine's CORE SNOMED subset, such as

some of the recent LOINC types of subsets. I can see the need to have maybe a couple around procedures, allergies, these sort of larger ones that are vetted and validated, whatever that means exactly, by national groups like the NLM, I think, help to give us a very good starting point.

I certainly think they're not going to be the only ones that are used, but it gives us a very good starting point. You know, there are 90,000 findings within the SNOMED clinical finding access, and being able to start with 5,000 to 6,000 of them helps the vendors out quite a bit. And it's also going to help out because one of the major issues we will see is the need to be able to localize these things. I think we all recognize that vendors, that hospitals, that even end user clinicians are going to want to be able to tailor these lists, and it's certainly much easier to start from an already vetted, smaller microcosm than the entire SNOMED access. And it's certainly fairly complicated to build these subsets, and I think that's going to help to simplify the process.

The other useful thing about having some of these sorts of larger starter sets, as I'm referring to them as, is going to help in the decision support arena as well. That many of these vendors who are building the decision support types of content, it'll be easier for them to focus on 5,000 to 7,000 SNOMED findings than trying to build their content to handle the entire SNOMED access. I think it's also going to be easier for the various kinds of mapping projects that we need to accomplish, to be able to focus on those more relevant and perhaps frequency based types of terminology subsets.

But with that said, I think, once we start with that kind of larger set of convenience subsets, we're going to have the need to localize these, and the vendors and the hospitals are going to want to be able to take these out, be able to add and extend to them, as they need to, for their particular medical specialties and practices. And with that said is going to come, of course, one of the biggest challenges. As I kind of like to say, it's easier to start using a terminology to begin with than it is to keep it up to date, and that is one of the biggest challenges is that there will need to be the requirement for each of these local users to be able to maintain the currency of their work as SNOMED, LOINC, and all of that change so that we don't drift too far away from the standards.

We do a lot of work overseas and, in the U.K., that's one of the lessons they learned about their read codes. That even though they started with the standard read codes, pretty soon they drifted away because they localization without maintaining the updating of that over time. And so, how do we do that? Well, I think that's the role that companies in the terminology services space play to help to provide the tools, the infrastructure, to be able to allow the different kinds of vendors and users to be able to receive and manage all of the subsets wherever they happen to be distributed from, to be able to update them, to be able to reconcile the local kinds of changes. These will all be important issues in terms of the terminology services.

One sort of final plug, and I know we've addressed a bit about the sort of what's the ROI. Besides the monetary aspects, I think that one of the challenges we face is that we do need to provide value back to the end user for using these subsets in the first place. After all, I don't care so much that I'm using a SNOMED code. That might help interoperability, but it doesn't provide me any value immediately when I've got a patient in front of me. What does provide me value is access to decision support content, care guidelines, protocol, improve patient safety, and having the use of the terminologies and the subsets is going to make it easier to build that kind of value content around them. Thank you very much.

Betsy Humphreys – National Library of Medicine – Deputy Director

Thank you, Brian. Frank?

Frank Naeyemi-Rad – Intelligent Medical Objects – CEO

Thank you very much, Betsy. I'm Frank Naeyemi-Rad. I'm with Intelligent Medical Objects. First of all, I'd like to thank you, Betsy, for, in 1995, providing IMO with a contract, and to work on UMLS and clinical terms within the UMLS. It was a great experience for my team and our company as a whole.

Obviously the fact that there are two people from IMO, I'm going to make my comments much shorter and allow our chief terminology officer, which is Chip Masarie, to actually provide you more detail. But one element that I really want to emphasize here is the role of practicing physician, practicing clinicians in whatever decision that are being made. We have to make sure that applications that are delivered to the practicing are not challenged by rules and regulations that we provide to them.

Creating a subset and target is great, but we want to make sure that we connect with them as real time as possible, provide their comments into our future and our decision-making. My one minute is over. I'm going to pass it to Chip.

Chip Masarie – Intelligent Medical Objects – CTO

Thank you, Frank. I'm Chip Masarie, and thanks for inviting and allowing me to tag along. I refer to myself as a clinically nonviable physician. I did two years of surgery training before I saw the light and got involved in informatics in '84. I had an opportunity to work with Betsy in the mid '80s on the first phase of UMLS, which was my teething on terminology.

I started my career really in informatics doing decision support, complex decision support with QMR internist spin-off and diagnostic work. Realized that we were a little bit ahead of the curve in 1990, so went to work for First DataBank. They acquired our company, so drug decision support, I thought, well, that's a no brainer, you know.

Well, after four years doing that, and people weren't using drug decision support, I thought, well, you know, EMR, that's, I mean, they've got to have EMR. So in 1997, I joined Medical Logic and worked for seven years doing EMR work and realized that that was not a slam-dunk either, as we're finding in 2010. I had to really come back to terminology, realizing, let's get the foundation set.

Anyway, I think I want to tell a story of when I was at Medical Logic. We were building an Internet based product, and I was asked to create a starter set for problem lists because it was lightweight. We couldn't hit the server. We had to load everything local, etc., so give us the top 500 diagnoses for primary care. Okay? Fun task.

I created this really great list, pristine, etc., and this was a model ... Internet was a model where everything synched with the server every night. I saw, after one day, I saw degradation in that list because people couldn't find what they wanted. And this was great. As far as I'm concerned, any time I can look at real use, what people really want to say when they're unconstrained by a controlled list, that's wonderful stuff as a terminologist.

But the point is that it's not enough to simply say we're going to create a subset because there's a whole discoverability component to terminology, and we can have, conceptually have the things in the subset that we think are important. But if people can't access those things, in other words, if they're not searchable, or if they're not scannable in a reproducible way, etc. So I just wanted to make the point that it's not enough to simply identify the subset of terms, but you have to think about how people are going to access those things. And, as a terminology vendor, we can create the best terminologies possible with lots of indexing, keywords, etc. And we are reliant on our partners, our vendor partners, to actually implement them.

Now having been on the vendor side, it's not so easy to make changes. Sometimes making the simplest change involves several releases, and oftentimes being an informatics person, the things that we're interested in informatics fall down the list as far as features because we have to do things like HIPAA security and things like that. I'm half joking. Anyway, discoverability is very important.

I do want to talk about kind of, one of the things I realized, I talked to Brian, and I talked to Rob earlier. I said, so what do you, how do you define subset? How do you define value set, because I didn't really know? I had my own notion, so I thought we could come to some kind of consensus, and I realized that we actually couldn't, just between the three of us.

Basically, when I look at value sets, I look at value sets. I actually think that RxNorm is a value set for medication. I look at SNOMED as a value set for problems. Okay? Now when I look at subsets, and I also look at – and when we talk about value sets, we talk about gender. Some of them should be no-brainers, but everyone knows that gender value sets are not no-brainers. So it's really important for us. You know, if we start creating value sets, that there's a tremendous control. So I believe that the control has to occur on the value set space, and the subsets are really at the kind of let 1,000 flowers bloom. Thanks.

Betsy Humphreys – National Library of Medicine – Deputy Director

Thank you. And Dixie Baker.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

I'm Dixie Baker, and today I'm testifying on behalf of the informatics team at Science Applications International Corporation, SAIC, and we thank you for giving us this opportunity to provide our thoughts on this obviously very important topic. SAIC has been engaged in informatics standards and information technology development in healthcare, public health, and the life sciences for many years. So we know that the development and management of controlled medical terminologies and messaging standards is difficult and exacting technical work.

Achieving consensus can be time consuming, often involving heated debates, as well as formal validating and valid comment reconciliation. Standards developers can have strong, ideological biases that hamper consensus building, such as whether SNOMED or LOINC is better suited for coding a particular concept. Users' needs for granularity and precisions can differ for even seemingly simple concepts like ethnicity, race, and gender, as Chip just said. Defining value sets and subsets is use case specific and may be outside the responsibility of the SDOs themselves.

In considering how the industry should move forward to more effectively use and manage terminology subsets and value sets, we offer the following four points. First, when value sets are developed, the needs of clinical users and patient care should be given priority over the needs of secondary users and reporting requirements, including meaningful use requirements. Second, value sets should be developed and maintained by those most invested in their use and most qualified to define and maintain their composition. Third, adoption of value sets and subsets can be accelerated by providing services to facilitate their publication, updating, and access. Fourth, where consistency and use of a value set is essential to interoperability or meaningful use, it should be specified as a standard within the relevant EHR standards, implementation specifications, and certification criteria.

The development of value sets is not a one-time task that's undertaken and completed. It's a continuous effort by the healthcare delivery organizations and SDOs nationwide and worldwide. There's no single central location where need is established or emerges, and no central location where needs are satisfied. We believe that the best results in developing vocabulary sets will always be derived when clinical

domain experts are brought together with informaticists with strong competencies in all three controlled vocabularies, exchange standards, and software development.

As for who should review and approve subsets and value sets, we suggest that the secretary of HHS should use her authority under Section 3004 of the Public Health Act to adopt, as standards, subsets and value sets that are critical to patient safety, interoperability, and meaningful use. In addition, the HHS should provide facilities and services for enabling value set developers to register value sets for consideration of standards and for making adopted value sets available to terminology consumers. We believe the NLM is the most logical and qualified candidate to provide that function.

You asked us to share our best practices and lessons learned. SAIC gained valuable experience and understanding of the challenges in managing controlled terminology through our work in building the CDC's vocabulary access and distribution system, the PHIN-VADS, which allows value sets to be browsed and manually downloaded from a Web site. While PHIN-VADS is a big step forward in making value sets accessible, it's not an ideal solution for distributing value sets when considering the fact that a consumer may need hundreds of value sets to accurately encode and share semantically interoperable health data. Requiring a consumer to regularly visit a Web site to check for updates to their value sets is unrealistic.

As EHR technology, employing controlled medical terminology is adopted more broadly, the need for processes and services to facilitate terminology management and distribution will become more acute and pervasive. Several years ago, our informatics team persuaded SAIC to fund an internal research and development project to address this impending need. Using UMLS as our authoritative source, the software suite that we've built provides the capability for vocabulary consumers to subscribe to services that provide and manage the value sets that they require. After subscribing to one or more value sets, the consumer automatically receives new versions of those value sets in accordance with subscribers' delivery preferences.

For a CMS sponsored quality reporting scenario that'll be demonstrated at the IHE interoperability showcase next month, we've integrated our terminology management and provisioning service with the health quality measures format, HQMF, processor and an EHR repository to produce the Stroke 3 quality report. We've now completed three years of IR&D on this service, and we're exploring ways on how we can openly and productively share our concept, our data model, our software, and our lessons learned with the informatics community.

Finally, regarding the role of the federal government, we suggest four roles. First, federal policy is needed to shape and guide the adoption and use of terminology standards by the industry. Second, federal funding is necessary to eliminate barriers to adoption, including providing national licensing for necessary standards such as SNOMED and HL-7. Third, the federal government should either provide or incent an open, collaborative infrastructure for contributing, developing, maintaining, and distributing terminologies, value sets, and subsets. And, finally, we recommend the government undertake a comprehensive review of federal healthcare regulations to identify provisions that may hinder the adoption of healthcare standards. We believe the Clinical Laboratory Improvement Amendments, CLIA, may be a good place to start.

Again, I thank you for giving us this opportunity to share our experiences, lessons learned, and opinions about how to facilitate the use of controlled medical terminology to create semantically interoperable EHR systems and information exchanges.

Betsy Humphreys – National Library of Medicine – Deputy Director

Thank you.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Thank you all very much. I appreciate that. I will kick off our discussion period by focusing in on one of the main topics of discussion in our previous panel, which was centralized process control and the need for centralized. It was said there that we needed to establish clear ownership of processes regardless of whether repositories for value sets were centralized or decentralized. And I'd just like to get a reaction to that from our panelists.

Brian Levy – Health Language – SVP & CMO

One thing that I haven't heard so far that I've found fairly useful, and maybe sort of putting on my CCHIT hat is the role of HITSP or an organization like that. That is, I think it's probably unrealistic to assume that there's going to be central creation of all of these different kinds of subsets. I think the creation is going to depend on an organization's experience, financing ability to maintain it, so I think, in some cases, we'll see NLM. In other cases, we might see Regenstrief.

But what I think HITSP did that I found useful was to be able to say, okay. Given the landscape of subsets and value sets out there, and I think HL-7 also serves a similar role here, is to say, well, here's the subset or value set that we mandate or we recommend to use for this particular kind of use case. And I think that made it easier to sort of navigate the different kinds of subsets and value sets out there. I guess I'm arguing in terms of the process control to have an organizational structure like HITSP and/or HL-7 that can continue to make strong recommendations or mandatory the use of certain kinds of these subsets in certain kinds of places.

I think just one more thought, and I think that's going to be particularly important is, I think the practical side of me says that no matter how hard we try, we'll likely have competing in some cases, contradictory types of subsets out there. Having organizations like HITSP to be able to say, okay, well, this is the one that we want you to use for this case, I think, is going to make it easier for the vendors to be able to go out and find it and actually use it.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Just as a follow up to that, so it sounds as if you would then support the centralized authority, essentially mandating the binding of a value set to the content exchange message for that particular use case.

Brian Levy – Health Language – SVP & CMO

I do, yes.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Dixie?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

Yes, I certainly strongly agree that the process should be centrally controlled. And I think that certainly our work with CDC showed that this really does work. And I can give you, as one example, the example of laboratory reporting of infectious diseases.

You have the states, determining by law, which infectious diseases are reportable, so you've got one organization doing that. You've got the CSTE and CDC working with the states defining the subsets, the value sets that'll be used to report those infectious diseases, and you've got a third organization, HL-7, defining the messages that will be used to report those infectious diseases. So you've got three different organizations with three different roles, but the owner of the process is CDC. They establish, and even

across state as far as they use a lot of the same processes to report infectious diseases. I think that's kind of a good model to follow.

Robert McClure – Apelon – VP & CMO

This is Rob McClure here. This is essentially what I have advocated for, which is to have a centralized process, not necessarily a centralized place. That, I think, can be demonstrated by an initial centralized place. But as we've been hearing, so that example that Dixie just gave about the importance of the CDC being responsible for its own stuff, and similarly, I point to the NQF as being responsible for those things that are quality activities. To put quality related activities onto the CDC process doesn't make a lot of sense to me, or to make those people, literally those people responsible, but they should be all following the same approach.

They should have the same expectations. They should ideally have the same sets of tools, the same sets of, when I do a query, and I want to go and see all of the value sets that utilize a particular subset of diseases that I'm doing research in, to see that I can pull information from a quality set, as well as a public health reporting set, as well as something out of NCI on research. That makes a lot of sense to us.

And so, I think that having – where the social good here is that the government can say, here's the set of tools and processes all of you entities should use, and set up a process, perhaps like whatever fills the voice that HITSP has left that says here's the way this should be done. And we'll make sure all of you do it. Then those different loci can function with some autonomy, like Andy's epitope issue, and yet still have that centralized core that makes sure that the vendors can go and expect the same thing in each one of these places.

Lee Min Lau – 3M Health Information Systems – Medical Informatics

This is Lee Min. So what even does centralized authority means? I mean, I'm practical. When you give, and English is not my first language, so when you give me a term like centralized authority, I'll say, what exactly does that mean? You know. Step-by-step, if I'm looking for a value set for dosage frequency, do I go to this Web site? When you have a centralized authority, have you tasked somebody to do that? Is that who I throw stones at if I'm not happy with? You see all of these details.

We can't even really agree on what the word authority means or what the word, like we were just writing here. You know, when you have a value set, are you talking about a reference set that start with comprehensive and then locally you pick the ones you need versus a starter set? You start with the most common and then locally, and you extend with things that you want that isn't in there. I mean, a lot of these things, we use the same words, and we don't necessarily recognize that we don't even mean the same thing. Sorry to answer a question with a question, but what do you mean by central authority?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Just to respond to that one, I think what we had talked about in our last session was that the centralized authority would be essentially a government or government sponsored entity that had both regulatory authority and funding to mandate effectively and to fund the process controls.

Chip Masarie – Intelligent Medical Objects – CTO

This is Chip Masarie. I've had several experiences over the years of looking at knowledge sharing opportunity, and both of them have failed. One was at Medical Logic when we basically put ... into the user community, posted forms and templates and things to share with the community. The other one was a decision support kind of sharing thing that never really got off the ground.

I think it's really important for us to be able to stand on the shoulders of other people who have done knowledge work. I'm a strong believer in a central kind of Web based toolbox, tool bench for people to be able to see what the other people have done so that they can start what other people have done. They can tweak it. It all gets stored, so in other words, the next person comes in, gets the benefit of – and I'm talking mainly of convenience subsets.

I'm not talking about value sets because I really believe that value sets, this should be still part of the same site, but the value sets needed to be controlled, and I'm talking about the shorter ones that are supporting your quality measures. Those value sets need to be might tighter controlled.

But as far as convenience subsets, I really believe that people need to be able to search, see what's available, what's the intended use of those things, and be able to pull something off the shelf and say, I want to start with this. And I want to take it from here. And then, under the table, you guys are watching to see what people are doing, so you can start getting frequency data. You can start putting together better sets because these sets are going to be starter sets.

Invariably, any healthcare organization, most healthcare organizations do not have internal expertise in terminology, so they can't create these things de novo. So they want starter sets. However, as soon as they get a starter set, they're going to want to tweak it. So, in other words, it's just an ongoing process.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Great.

Frank Naeyemi-Rad – Intelligent Medical Objects – CEO

One of the factors that I think we have faced is really the use population and the vendor population were disseminating and distributing there. I think I believe the distribution of the service should be in distributor mode. Centralized, but distribution should be put in private sectors, and allow private sector to compete in distributions, get information back, analyze the data, not necessarily from sampling and analyzing the outcome of the data, but analyze, understand what the intents are, and communicate that to the vendor community. Make sure they implement the stuff correctly, and then bring the data and result finding back. I would say distribution should be done through distributors.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Thank you. I think it was Chris and then Floyd and then Chris and then Doug.

Chris Brancato – Deloitte – Manager, Health Information Technology

Thank you. Actually, I found this very helpful in listening to all this discussion. I was a little confused in some of the comments that it wasn't clear to me that there was a separation between a value set and a subset, as Betsy first described at the beginning of our meeting today. And it seemed there was some fuzziness in that definition in some of the presentations.

But what I'm going to address is the value sets, which we just heard was something that you would use when you're defining something specific you're looking for. And my question is directed somewhat to Dixie, but anybody. Understanding that PHIN-VADS has developed value sets for specific reporting of reportable disease, and knowing we'll hear about, I think, in the next panel, and I heard some talk to that about share for research and FDA reporting. And then there's also the quality need.

How would you deal with value sets that, for the exact same meaning that might be a quality measure looking for an output that's the same as the reported disease that's also used in research? Are you

thinking of some, in governance, some coalition of the kind of three areas or multiple areas? How would you approach that?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

Actually, I think it's Rebecca Kush has a nice diagram in her paper that shows exactly what you're talking about, and that really brings home my comment about clinical uses. There's overlap, but then the clinical use is kind of a larger. That really should be the focus. And I think, in our organization, our team absolutely agrees that the focus should be, how do you improve care, and how do you improve the health of our population? And all these other are secondary uses, so they're extensions that provide extensions of the vocabulary and also bring context.

This is where ontology comes into place. You can have the same set of value sets, but depending on your context, it may even have different meanings. I think, between, you have different value sets. You'll have overlaps in the value sets. And I think each one, each value set has its own context.

Chris Brancato – Deloitte – Manager, Health Information Technology

Can I just follow up? I guess that's understood, and I'm familiar with that drawing. The question I have, though, is how would you manage the governance of the process to make that happen? What's your recommendation?

Brian Levy – Health Language – SVP & CMO

Just to maybe provide some of my thoughts on that, I think that is going to be a challenge.... I think, no matter how hard we try, there will be contradictory and competing types of value sets, as well as the different kinds of subsets out there. I think some of that can be handled by organizations such as HL-7 or HITSP where we say we have actually bound this particular value set for this particular use case or this part of the message or this part of the CCD document. But even with that, there's still probably going to be confusion out there as to, okay, well, these two, I understand where I use this value set. I understand where I use value set B. They're kind of the same thing, but they're not exactly the same thing.

I think there's probably going to have to be a commercially driven process that is the EMR vendors and us providing feedback to the organizations that create and maintain these value sets to encourage those organizations, whenever possible, to sit down and try to share there. You know, can there be some overwhelming one central group that coordinates and maintains all of this? That would be helpful, but probably unlikely to happen here.

It does happen to some extent in the national health service over in the U.K. They recognized certainly early on with the adoption of SNOMED that they wanted to be able to create many different kinds of SNOMED subsets, and in fact they've created about, I think, about 100 different SNOMED subsets so far. What they do is they create that from a central. They do create that within a central group. They elicit feedback from the different medical specialties within the U.K., and then they distribute these subsets from a central process. It's still early on to see if that's going to work or not. It'd be nice to do here, but I think it's probably not realistic to have that kind of central authority happen here.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

I think it's very realistic. I mean, to have a core, what you're referring to as starter sets, a core set of terms that all of these stakeholders use. You know, if that overlap between them should be controlled as a starter set, and everybody can build onto that. But the core that's overlapped should be controlled, in my opinion.

Lee Min Lau – 3M Health Information Systems – Medical Informatics

This is Lee Min. Just responding to the potential confusion between subset and value set, I don't think Betsy's definition is extremely clear. There's no confusion there. The reason why we go straight into it about our lessons learned, our perspectives and ... as terminology services providers, we like to think we're coming at it from the actual implementation, the user's point of view. I can tell you, they don't care about the difference between value set and subset.

They come from a perspective of taking baby steps one at a time. The first thing they worry about is can I even get data out of my system. Never mind what the data looks like. Can I even get it out? And then when I can get it out, then how can I get it out? Am I getting it out as tags? Am I getting it out as what?

And so the next thing they worry about is the messaging center. So from there, if you want to think about it this way, they probably just go straight to a value set. This is the data we want to send. This is the whole set. Just deal with it, and whether it's a standard or not, whether it's a subset of a standard, whether it's a value set, a combine ... subset ... standard, I haven't seen an end user who really cares unless it's someone like Stan, you know. I'll stop there.

Robert McClure – Apelon – VP & CMO

Before you get in trouble. Rob McClure here, a couple things. One, the reason that this whole subset and value set thing is never going to end to some degree is because, in my opinion, when you look at a list of concepts or however you want to look at it, a hierarchy of concepts, you would not be able to tell whether it's a subset or value set by looking at it. It is all about how it's used. And, to some extent, how it's defined, and not about what you're looking at. That's why the same list of concepts, when we talk about it in one context, we're talking about as a value set because it's tightly bound to an information ... for a particular use.

That literal same list could have been set up by IHD SDO about when they say this is the list of things that we say and are in our terminology that represent organisms. In that context, in my view, that's a subset. But that exact set is the same thing that you're going to use if you're now binding it to an information model for a particular use. It becomes a value set. So there's an orthogonal attribute to these things that sometimes gets lost in a general conversation as to why they seem to be the same thing. They are the same thing when you take them out of context.

The other thing is that it is really important to reiterate this alignment of various stakeholders that it requires, in my list, three kinds of entities in order to create something of value in the context of subsets and value sets, particularly value sets. One is, I keep trying to come up with a general way of saying this, but I'll call it an exchange requirement definer. By that I mean, you know, a quality measure developer. Someone who says, this is what I want to exchange, and here's exactly what I want to do with it.

Another might be the CDC in terms of reporting requirements, or the state entity with regards to their specific requirements, or CMS or HHS with regards to billing requirements. These are people or entities that are defining the exchange requirement and what is needed. To that mix, you must add model developers, so the HL-7 folks, people that know how to create and define all the elements of a CDA in order to be able to actually do that exchange or the message developer. And finally, little old us, the terminology geeks who understand, okay, when you say that, we can do this in more than one way. Which way do you want to say it? Then, once we've done that, what's the list that fits out of that particular terminology?

Then, most importantly, because we've talked about this, how do you maintain it? What's important about its lifecycle and those sorts of things? And you have to get all three of those groups together. We found this quite clearly in doing the HITSP work based on the CMS project that NQF did in order to get

those 16 quality measures done under that tiger team. In order to retool those quality measures, we needed to get the measure developers, the modelers, and the terminology folks all together, back and forth, before we finally came up with an implementable way of exchanging information.

Once again, doing that, it shouldn't be that CDC figures out how to do it for public health. That NQF, again, figures out how to do it for quality. We need to have one approach that's centrally governed with reusable capabilities and components, centralized access, whether it's a Web page, but it may go to different places in order to actually get the information. Centralized expectations with regards to updates and vetting, and I am of strong agreement that we need to take these all the way down to seeing them implemented, and see that they impact patient care. All of that is best done by the government because it's a collective value that you're talking about, not any single entity's side.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Thank you. Chris, I believe you were next.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards

Thank you. Much of this discussion is reminiscent, as many of you know, of the U.S. realm discussions and sub-realm discussions that have been going on for as long as I can remember. But toward that end—

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I think you've been causing them.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards

That's why I remember them. Toward that end, this question of how terminology services and whether it's distributed, decentralized, I mean, this touches on our discussion this morning. As you know, the emerging fashion trend in terminology services this week is the notion of distributed terminology development and the cooperative groups using common services, common calls, and common methods and proposal based efforts, which gets at the boundary between user input to a content developer and then down that slippery slope to a community process, an analogous in some vague way to Wikipedia for the joint development of a common product with slightly more rigorous governance structure to make sure that there's harmonization, consistency, and reasonableness through the whole thing.

From the perspective of terminology services, and that is our title, how do you see that playing out in the United States over the next four to five years, specifically user communities, realms, sub-realm communities collaborating on a joint effort with central authority—yet unnamed, I recognize—to collaboratively develop and refine this kind of content, because one of the issues that you've all emphasized, and I certainly have learned it myself, is the naughty problem of maintenance. It's not sufficient to generate content. It's really handy if you can keep it up to date.

Brian Levy – Health Language – SVP & CMO

Yes. Just to add to those thoughts. I think we also have to be careful on who the user is there, who would actually do that. And so, you know, it's sort of like, as a terminology service extender, we built lots of tools that help sophisticated terminologists create subsets and create mappings and all that. But what we've also found is that there's sort of a new set of users out there, and that is the end user hospitals, the clinicians themselves who actually need a very different set of very simple tools because they don't want to be exposed to all the complex problems of the SNOMED hierarchy and all that.

To sort of answer your question, I think it would be useful to have expert domain users being able to contribute in a Wikipedia type of way to creating these kinds of subsets. I think we probably don't want to

expose, or it's probably unlikely that the sort of end user base is going to want to or be able to sufficiently contribute to that process as well. We might want to feed back what we're seeing sort of in the field.

The other question though is that, honestly, how many folks out there have the expertise to contribute to this? We find building SNOMED subsets actually fairly hard to do it right, and so as good as an idea that may be, how many folks out there would actually do it?

Lee Min Lau – 3M Health Information Systems – Medical Informatics

This is Lee Min. I maybe have a different perspective coming from the data world, so as I said, first love is to data. Second love, terminology, I guess husband is now third. So what terminology exists to do is to encode the data, so we can do something with the data. So from my perspective, for instance, it's the people who are going to own the data that really call the shots. If they say this is what we need and what we want, it doesn't matter if it's found in a standard or not. It doesn't matter if I personally agree or not. It has to be there, so they can encode their data.

For instance, this is from a long time ago, which is a little bit strange. To this day, I have had one customer who insisted that there is such a thing as a CT scanner for a thumb. I don't think so. The best you can do is a whole hand, and even think that's doubtful. I don't care because that's the only way I can see that I'm zooming in on a thumb, so I want a CT of a thumb. You know, so CT of thumb it is.

I have another customer who just does CT upper limb. That's enough. So it is really down to the ones who care about the data. So if you ask me who gets to decide who gets the governance, at least from a provider point of view, terminology provider point of view, we have to make sure that the data at the end is at the granularity that they need. Then, in the terminology side, we can build the knowledge base, build all the relationships that we need, do all the mappings that's needed to give them that knowledge base that they can use then to manage the data. But I could not, right at the beginning, tell them that they don't get to say what kind of terminology will be used at what level to include that data.

Robert McClure – Apelon – VP & CMO

This is Rob. I would just add that obviously this is a somewhat complex area, but it really centers from what Lee Min was just talking about. I think that we have to create an environment that makes it easy, but the folks who get to have a say are those who are actually asking for the data primarily, so that it's very clear, this is what I want. And there's a sequential process. Then you bring in the organizations that are going to have to deliver that information. You say, does this make sense to you? How can you do it?

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards

...clarification, by asking for the data, are you talking in the context of secondary use or the primary clinical use because...?

Robert McClure – Apelon – VP & CMO

I think it doesn't matter. For example, in the context of exchanging information for clinical use, those that are interested in saying here's the data that we need, it could be, you know, clinicians. It's going to be that they're going to turn around and say, and now I'm going to have to provide it. But it's absolutely fine.

Remember, and you know this, Chris. This is about what we can encode. We encode what we can use. I think we're at the very tip of an iceberg, and it's really easy for us to slip down the slope and start thinking about talking all of clinical medicine, when we need to be very careful. We need to only solve what we need to use as a computable thing. I can do something with this if the computer understands it.

We absolutely need to exchange information, so clinicians can operate on it. And we should not mess with that. All we need to do is pick out, you know, oftentimes you encode at a higher level of granularity because your systems don't need that specific information, and so this is a very hard thing for all of us to keep in mind. That's why I think it's really critical that those who are going to use the data be primarily responsible because they'll throw up their hands and say whoa, whoa, whoa, whoa. You guys are going way farther than what we need. Stop. And you'll stop sooner.

Lee Min Lau – 3M Health Information Systems – Medical Informatics

Well, I have an opposite, well, maybe opposite is not the right word, but the part that I keep wanting us not to forget is the complexity behind it all. And I wanted to make sure I'm very clear as to what I was trying to explain. It's probably impossible, but take a lab result. We all know we're going to try to, if not code to LOINC, at least follow the LOINC nomenclature, which means there are going to be lab results out there that does not have a LOINC code on, and will never have a LOINC code. It doesn't mean we don't create that concept according to the LOINC attribute, and make sure they have those LOINC attributes.

The problem is, if you only – and say – let's just stop at the subset, say, from LOINC, and nothing else needs to be considered. You will have this unintentional consequences of people just forcing a fit to just that set, whereas the right way to do it really is to embrace the complexity. Know that every lab result should have at least five to six attributes in a messaging option.... And if you cannot exchange one-to-one using LOINC codes, then for goodness sake, exchange the attribute because you can see they share the same analyte, or they share the same specimen or whatever. But you don't force that fit, and that's why we keep saying that this is a problem that has to be solved with a lot of education or maybe some acceptance that is not going to be solved. It's just going to be managed.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

Could I just speak directly to your question, Chris? I think clearly that collaboration is the right way to develop the value sets, and clearly there are millions of ways that you can express a lab result or whatever. But I think that it's important that we think not just about as – coding information is not the objective. Coding information is a means towards an end of whether it be sharing information, clinical information, whether it be reporting results, whether it be research or whatever. And because it's just a means to an end, there is a need for us to have, to just decide on and have someone to decide on. These are the standard value sets we're going to use. Yes, there are ten other ways we could do it, but these are the way we're going to do it because we won't achieve interoperability, and we won't achieve secondary use even unless we have somebody step up and say, these are our standards.

Brian Levy – Health Language – SVP & CMO

...add to this point. I think what we're sort of wrestling here is that there is a balance between saying we need all these different types of value sets for reporting purposes, and yet where is the data going to actually come from? Well, someone is going to have to sit there and enter the data. And as Rob said, and I also completely agree, we don't want to go overboard there. We don't want to require too much structured data entry at the point of care to the point where the clinicians say, well, this is just not worth my time.

We need to provide some kind of balance to say, okay, if you spend some extra time entering in some of this data, you'll provide value in terms of interoperability, but we also need to provide, as I said earlier, some value back right then and there for that extra time. It will be longer for us to enter in information in a structured way into an electronic medical record than it will for me to write and scribble something in the paper chart. And so there needs to be that sort of balance to say, okay. It's great. We can come up with all these quality measures, but if some of them are maybe not so relevant to me right then and there, I

may not want to spend the extra time to enter in the information that's necessary to report that in the first place. So there is going to be a balance there. We don't want to create too many value sets and make the process overly complex.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

But think about meaningful use not – stage one is quality measures. Stage three of meaningful use is clinical decision support. You've got to code a lot of information. You've got to have a lot of structured information to be able to support that.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Thank you very much. Doug, and then—

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics

...go back. I'm going to go back 45 minutes in our discussion and try to ask that question that came up early on. I'm going to direct this question to Dixie and to Robert McClure, and others can put up their card and answer so that we can get to the point that Stan can get his questions answered as well.

Dixie, you said that we ... central processing control, and you gave an example of three different organizations that affected at different levels of semantic interoperability. You sort of described kind of information models, transportation models, and value sets, and you gave examples of HL-7 and vocabulary, and I can't remember what the other one is.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

Yes, three roles that are involved in the same measure.

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics

Sure. And that one can argue that if you had a central processing control and engaged people across that spectrum, what you would do is you would have that process, but then you would get quality reporting in and other sorts of things to sort of work within that. Now Robert described kind of the same scenario, but he used different examples. What he said was that you have sort of different organizations or domain experts, and so he was concerned that quality reporting, research, public health, you know, maybe—

You know, so the example might be, suppose we wanted to do something around diabetes. We want to have interoperability around measures reported to diabetes. And there might be quality reporting measures. There might be interest in clinical research around that, and there might be a public health reporting component of that.

When I think about the centralized process, there are two ways I could structure it. One would be to say I'm going to get information models, transportation, and value sets, and I'm going to use that as my organizing principle, and I'm going to have the different domain experts work within that. So quality reporting will work on value sets, and quality reporting might work on information models, but sort of the ownership is of that larger group: the information model, transport, value set. The other way to look at it is to say, we're going to take quality reporting, and they are going to develop an information model, transport, and value set. And we're going to look at research, and they're going to develop an information model, transport, and a value set.

What I'm trying to understand is when you think about this central process control, is the owner the kind of level of semantic integration that you're thinking about so that there's a value set group and there's an information model group? Or are the owners the domain experts like clinical research or quality reporting

or American Diabetic Association? I want you to sort of, you know, help me understand what you're thinking about when you're thinking about this because both of those aspects are important. I just don't know exactly how we're thinking that this should be organized.

Robert McClure – Apelon – VP & CMO

You can go first, Dixie, if you want. I have a very clear answer about what I want to say.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

Thank you. Why don't you go with your answer? Let me think about it.

Robert McClure – Apelon – VP & CMO

This is exactly what I was trying to get at. It's really hard to make this clear, so I apologize. Perhaps maybe that's what it is. But I believe that—you're going to hate me for saying this, but—it's both. So what it is, is that the domain experts have the most knowledge. That they're the ones that are responsible for clearly identifying the information that they want exchanged. What's valuable to encode? You keep hearing me come back to this.

They are not supposed to be, nor that I would hope we would never expect any of those domains, and certainly God help us if all of the domains independently get experts on those more technical areas. I break it down, as you saw my list was essentially the domain experts, and then experts about how you model the exchange of information. Perhaps that's similar to Dixie's second transport thing.

In our more SDO focused way, it would be CDA experts, or it could be messaging experts, or if you're down in Australia, it could be architecture experts or whatever. But it's someone that understands how you actually define and exchange the information because it gets to this issue about is there one slot for problem or multiple slots for problem. Then also, then there are terminology experts that all these people have some knowledge. That's why it's great to have people who have some clinical experience in every one of these areas, but they're not meant to be the ones deciding what are the important things to exchange about diabetes. But you bring those groups together.

Now what I've been pushing for is that those last two things, those things that are about the exchange format and the terminology, and to that I would add the governance and infrastructure that hangs all of that together. That is actually your responsibility, Doug, because that, by doing so, you provide all those domain experts something that they don't want to know. They just want it to work. And by making it consistent, you achieve exactly what you said, which was my goal, which is that when you're done across multiple domains.

When I'm a clinician out in Colorado and, decades ago, started to get involved in a collaborative group trying to capture patient data to do physician practice oriented research, then I can go in and say, what are these groups that are interested in doing quality, doing public health reporting, doing drug research? I'm interested in doing my domain is diabetes. What are they interested in collecting? I can do queries and see what are the models that they're looking to exchange. What data have they already gone out and pushed vendors to try and begin to capture?

Once again, that infrastructure piece is a common good that needs to be developed and establish a governance process that I strongly believe is the government's must do. And then they make that available to domain experts with guidance about where they want to do it and why, and we see it's not going to be just throwing it out there so that every clinical institution that has some interest can go and do it, but it shouldn't preclude it. We just know that NQF should do quality. We should know the CDC is to

public health. We know NIH should do research-based things. But if a little hospital out in the middle of Wyoming wants to do something, they have a place to go and look and see how it's done.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Dixie?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

I think the word domain is way overloaded, but it sounds like you're using it as referring to a particular medical domain like diabetes. Is that right? I think, as I said in my testimony, that the value sets should be developed and maintained by those invested in their use. I think that the federal government can establish a process that will work across various uses. Value sets, I believe, are use case oriented.

You may have a domain expert in diabetes that works on a value set that's used in meaningful use reporting, and another domain expert that's used in developing a value set for clinical decision support in diabetes. So I think that the process should be defined in a way that it can be used for a number of purposes, use cases, if you will. And I totally agree with them that the government should provide the process, and should provide some infrastructure to really developing the value sets and the use case.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Great. Thank you very much. Stan and then Clem and then Betsy.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

I hesitate to say this, and I don't want it to be a rat hole, but what occurs to me is a question about whether, in addition to the definition of value set and subsets, we also need to create a few more definitions that create some other common – and I'm thinking, do we need a name that says basically are we doing these things as concept-based things, and what do we mean by a synonym, and what do we mean by--?

I think there are good examples out there, but I think, at least for communication in this group, we sort of need a terminology of terminology that goes beyond just saying value set and subset. We need to sort of ground that in some other things like concept, synonym, code, and part of it comes out as Intermountain has worked with Mayo Clinic on some of these things. We found out that you actually have to get down to basically almost formal notation and say this is a code, and it seems like we might need to get to that level as part of this, and I absolutely don't want to talk about specific definitions today, but do you think we need some definitions like that to sort of ground the rest of this discussion?

Brian Levy – Health Language – SVP & CMO

Just to maybe not go into it in too much detail, but for example, I certainly sense the need to have distinctions between term-based subsets and concept-based ones. For example, as I mentioned earlier, we're going to see the need to have localizations. Part of that localizations is going to be the need to say, well, this is the way I say something, and it's my local term. And we're going to want to provide a mechanism for them to at least attach that term to a concept in a specific terminology. Now whether or not this group needs to go into that much detail now, I don't know, but certainly those are going to be the issues that we're going to have to face over time.

Frank Naeyemi-Rad – Intelligent Medical Objects – CEO

Going back to what Betsy said at the beginning, the fact that there are terms that may not be included in the subsets and value sets, and an ability to be able to capture the intent. And, as part of messaging, making sure that those intent are followed, I mean, by giving the SKUs to the vendors or anybody else to kind of chop out the meanings because if there's a local mapping, and those mappings are incorrect, how

do we know? So we want to make sure whatever we do, not lose that intent that was captured at the point of care.

Robert McClure – Apelon – VP & CMO

I want to just, real short, you know, there are a lot of really bright people that have been dealing with this for a long time in this room, and I'm sure on the phone. We cannot solve all the problems. I mean, one of the things that, as a group, we tend to do is, as we start to talk about this, we start identifying all of these things that once we've done X, Y, and Z, Q is going to be a real pain in the butt, so let's talk about Q for a while. Well, but, you know, I would really like us to actually solve X first. And we'll see. I bet Q won't even really be around by the time, and we're all going to be dealing with the Alzheimer's problem ourselves before we get to Q.

So I think, you know, we all enjoy this, clearly, a lot, I mean. That's why you get this group to talk a lot. But I think that we really need to accomplish some, I'll call it, basic things. And we need to be very cautious about worrying about the problems, once we've solved those things, what we're going to have to deal with. Gosh darn it. Let's just do something.

Lee Min Lau – 3M Health Information Systems – Medical Informatics

Yes.

Clem McDonald – Regenstrief – Director & Research Scientist

A comment and a question to group ... setup for the question, so there are a number of tensions between this side and that side, and I've heard two tensions described. One of them is between coding everything, so anyone can do anything they want with it. The other one is not coding everything so that people can actually leave the office, you know, once a day for five minutes. So that's one tension.

The other tension is, as what was described as, you know, we really have to let them say whatever they want to say, and having some constraint on what they can say, so the other person can hear it. As an example, in LOINC, we've been pretty open. You know, we just kind of take what people want. But lately, we start to sense the problem of the coders, the mappers. You know, why do you have three variants to this? And someone recently asked for a test called either CSF or serum for coccidia.... And it's a nice place. It's a good place for a test where it makes a difference whether it's in the brain or somewhere else because....

We're going to take a little ... to say, no. We're not going to do that. Why don't you make up two codes because we already have the separate ones anyway, you know? So there is that tension. And I'm wondering, though, how do we get the tension? You know, the marketplace kind of is one weight of tension ... so much, people decide that. But we're taking the marketplace out of this, at least regards to the physician. They can't say no to these things.

How do we create the tension to find the right amount, and the domain guys actually scare me to death. I'm going to give you one story from like 1974. The people did quality assurance studies, and the guys decided at the airport what was good quality for a urinary tract infection. They made a list of 22 things you had to do to treat every urinary tract infection, and everybody flunked that they tested that against.

Then they went back and looked at the guys who invented the rules. They all flunked too because, in fact, what you do is if a woman says I think I've got another urinary tract infection, oh, well, I'll send you an antibiotic. I mean, you don't have to do all that stuff. So when the experts get together at the airport, they think of everything they know, and they show off, and ... these are the things we've got to get, and that's going to kill the clinical guy trying to get home once a day for five minutes.

Robert McClure – Apelon – VP & CMO

Yes. But, Clem, that's not our problem. That's just a problem in the process that that's certainly out of scope for this discussion, but it's an absolute problem in building quality measures and that sort of thing. I think that gets to my point, which is, we can't solve all of these different problems. We need to – you know, this is about providing the infrastructure to support when someone starts to do this, we'll figure out how to actually make it better. I honestly don't think we know yet.

Brian Levy – Health Language – SVP & CMO

Yes, I mean, one other thing that I think a couple of us have briefly touched on is that I think there's a big need for best practice guidelines so that we can say, okay, here are our recommendations. Here's how you should go about building a subset or building a value set. Here's who you should contact regarding trying to bind that to an HL-7 or CCD. I think, having those best practice guidelines come out from this central group is going to be hopefully extremely helpful, and hopefully folks will be able to adhere to those guidelines.

Chip Masarie, Intelligent Medical Objects – CTO

Clem, I just wanted to respond to your request for the CSF or serum. When I was responsible, our strategy at Medical Logic for terminology was that we managed. We basically had problems, medications, and procedures, and then there was everything else, which we called observations. Essentially that was the flexible place for people to develop data elements.

And we manage that space for people, so basically they input requests, and we had to create the terminology, and we had to make a decision. Is this going to the factory set, or does it stay in a local set? And I think that that kind of experience is, and there was a lot of pushback. We let them understand. And I'm not suggesting that you create that, but we had to deal with that all the time.

And I think one of the points I want to make is we are here to serve our customers too. Oftentimes the request that people will make, the things that they need are workarounds for systems that are not working the way they should. And so, I think, as a terminology vendor, and as someone who has been doing terminology for a long time, I have to keep reminding myself, people may be asking for these goofy things.

I mean, at Medical Logic, we didn't have a place for, for example, room number. People said, oh, we've got this observation space. We can put room number in as an observation. Well, you could say, boy, stupid, you know, blah, blah, blah. But the point was, they were just trying to do their work. So I think it's something we have to remember as terminology vendors is these people are trying to do their work, and they're doing what they need to do. They're asking what they need to do in order to do their work.

Clem McDonald – Regenstrief – Director & Research Scientist

So this first one ... say no ... I probably can't say no?

Chip Masarie – Intelligent Medical Objects – CTO

No. It just reminded me of the experience that we had of having to kind of get these requests and say, wow, why are you asking that.

Clem McDonald – Regenstrief – Director & Research Scientist

I'd still like to go back to, you said it's not our job, but you all said we don't want to have too much. We want to have this much, not too much. Is there any rule, maybe just that's good practices, or any

structure that you can build, or anything you can suggest that would have it come out that way? You'd have it...?

Betsy Humphreys – National Library of Medicine – Deputy Director

We're going to appoint a panel. We're going to appoint two or three czars and czarinas.

Lee Min Lau – 3M Health Information Systems – Medical Informatics

It's not our job to say no. It's our job to take what they want and make it work according to the informatics and terminology principles, so that Stan won't be throwing things at me when he sees me. That's the thing. So really, terminology service providers are a bridge. We basically just try to please both sides. And when we absolutely cannot, then we basically say no and duck really quickly.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Great. Thank you. Thank you very much.

Clem McDonald – Regenstrief – Director & Research Scientist

...say no too often, you're going to be out of business.

M

That's right.

Lee Min Lau – 3M Health Information Systems – Medical Informatics

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Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Thank you very much. Now, Betsy, I think, had a final question, but I also want to ask our taskforce members on the phone if anyone else has any questions for the panel. Okay. Hearing nothing, and Betsy has withdrawn her question, so I want to thank you all very much. I really appreciate the spirited discussion here today, and thank you for coming in, and thank you for your written testimony as well.

We are now ten minutes. We ran a few minutes over on that. We have scheduled a 15-minute break. What I'd like to do is take a ten-minute break. We'll come back at 35 past the hour, and we'll start up again with our next panel. Thank you.

(Participants Break)

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Thank you, everybody. So for our next and final panel for today, we're going to hear from message standards development organizations about their perspectives on the same set of questions. Again, we want to focus in on the three questions of what the federal government must do, should do, and should not do for the ending of this discussion. Let me see if I can turn first on the phone to Bob Dolan to provide his testimony. Do we have Dr. Dolan? Okay. I guess we'll come back to Bob when he's off mute. How about if we go in order of the seating of the panel, so we'll start with John Quinn.

John Quinn – SCO – Chair-Elect

Thanks, Jamie. Hopefully Bob will materialize. Good afternoon. I've been asked here to testify on behalf of the Standards Development Organization's Charter Organization, or SCO, and yes, it's an acronym with an acronym. Sorry.

Most of you already know me as the CTO of HL7, and even some of you may realize that I am actually employed by Accenture. I'm one of the founders of HL-7 and dating back to 1987, I served as board chair, technical steering committee chair, and now CTO.

Efforts started several years ago during the previous administration to improve healthcare in this country, partially through the improved use of healthcare information technology. As part of that effort, HITSP was created as one mechanism to deal with the challenges of creating implementation specifications for defined interorganizational use cases. Characteristics of these efforts are that they use existing HIT interoperability standards such as HL-7 and CPDP, X12, and others. Use existing implementation specifications from HIE, and identify gaps that need to be filled.

Sometimes the SDOs are seen as part of the problem, primarily because the deliberative process is rather slow. Others are that we're volunteer driven, and people come usually to expend energy on things they're interested in, and the SDOs represent different vested interest of the same based pool of technology and scarce resources. It has become clear that it is important that the valid, valuable, and important role of the SDOs be clarified, that our collective commitment be clear, and that the complexity of these challenges and issues be explained.

In early 2008, Leanne Stember, CEO of NCPDP, called for a meeting of U.S. healthcare SDOs that was referred to as the SDO Summit. Many of the people in this room attended one or more of those meetings two years ago. To make it short, after a year of conversations, we decided to create something called SCO or standards, we just sometimes refer to as Standards Charter Organization.

The goals of SCO are to provide a basis for SDO leaders and their respective boards to be consistent in the issues and our value proposition to our industry, to provide a joint, agreed upon, common list of positions on SDOs, our value contributions, and current initiatives. In other words, to be something that makes things more visible, and that you can communicate with. And to provide the basis for formal communication that can be consistent from both the SCO members and their supporting SDO and press release activities. Provide a common basis for both formal and informal communications in key standards and issues. In short, if somebody has a question, an issue, needs something done by the SDOs, we wanted to give the SDOs a more visible group where people could communicate with us, where we could work and collaborate together, where it would be visible that we were collaborating together.

Skipping ahead, an example of projects that are now in process or in discussion among SDO members today within SCO, I'm going to use these to give you an example as to what's going on, so that might give you some idea as to what we mean by collaboration. One, a service oriented functional profile for provider registry, including stewardship roles. A follow on project would be querying for information more specific to the provider. Another one, participate in and complete a recommendation document on the code set to use for route administration for the HIT SP use cases.

Obviously that involves NCPDP, as well as HL-7, and NCPDP Script message to query with the HL-7 CCD or ASTM CCR that contains the patient summary information. In effect, this is the ambulatory corollary to what we did about four years ago with NCPDP in the acute care setting on discharge prescriptions. So in other words, take what's happening in NCPDP Scripts, put in a CCD, map it to the rim, show that you can work data through from HL-7 through NCPDP, and have a certain idea of exactly what it is you're doing and working on.

And, as recently as last week, HL-7 WEDI X12 collaboration to take the information in a HIPAA 837 claim transaction and map it to the HL-7 rim. This actually is easier than it sounds because HL-7 has a set of claims transactions that are used outside the U.S. by primarily Canada, Australia, and New Zealand, that

are already version 3, in the version 3 standard, the current normative standard for version 3. So given that there's a fair amount of commonality in terms that are being exchanged, it gives us a basis for rather quickly moving that forward.

The current SDO members are listed, except in my attempt to alphabetize it, I left CDISC off the list, and so my apologies to Becky. And you can also see that there are a number of organizations, including ONC and HIE and the ISO TC215 US tag that do participate in these meetings, as well as observers. I would actually personally like to see them observe as a little more forcefully than observers in some cases, especially ONC, to be perfectly blunt and honest about it. It would be helpful.

I wanted to just reference my answer to question eight as well, not that I want to spend a lot of time talking about it. We can talk about it in the panel, but this goes to some of the questions that were in the last panel as well. But the NHS, as of 2006, had over a million active terms they were maintaining. They were updating that set of terms. I realize that SNOMED and REIT codes, and there are all kinds of other differences. But the only point I want to make here is that they are doing about over a million transactions a day on the spine now, and much of that is clinical information: all e-prescribing, e-bookings, which includes clinical referral information, as well as the rollout of their summary care record, which is their equivalent of our CCD. So there's got to be something worth looking at in what they're doing. Thank you.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

John, thank you very much. Before we go to CDISC, I believe we now have Bob Dolin on the phone. Bob, can we hear from you next, and then we'll...?

Bob Dolin – HL-7 – Chair Elect

I hope so. Sorry about that. I was on the Internet thing, and I guess you guys couldn't hear me speaking. My apologies. Shall I begin, Jamie?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Yes. Please go.

Bob Dolin – HL-7 – Chair Elect

I wanted to make a couple of disclaimers up front. I did not have time to get my comments officially endorsed by HL7, so I'm really going to be speaking on behalf of my HL-7 work, my prior Kaiser work, and the work I've done as cochair of the HITSP foundations committee. I anticipate that official HL7 feedback will be coming in by the 5th.

Also, I just wanted to point out, you have my written comments. Here I wanted to maybe take a step back or maybe you're going to hopefully not call it digress a little bit to talk about what I think is particularly relevant. Jamie, when we've talked, you've always emphasized to me that your key focus in the vocabulary taskforce is resolving the notion of value sets, particularly to achieve what's necessary for meaningful use. To me, when I think of meaningful use, what I think of is data reuse. I try to think, therefore, when we look down the road two years, three years, five years at the framework that we've envisioning developing for semantic interoperability in the United States, where do value sets come into play? What can we be doing today that helps take us a step forward towards this, you know, down this road?

With that theme in mind, I hope these comments, while they're, on the surface, not directly related to value sets, I hope you see that they really are quite relevant to our decisions around value sets. There are really four points that I'd like to make here in my oral remarks.

Number one relates to global vocabulary standards. The primary impediment to the creation of global standards within HL-7 is the lack of a global terminology standard. From my perspective, we really need to start thinking about at least virtual integration between terminologies such as LOINC, SNOMED, RxNorm. When HL-7 ballots a global standard, we get dinged if we use LOINC, whereas if we ... a U.S. realm standard, we get dinged if we're not using LOINC. The absence of global vocabulary standards makes it difficult for us to support meaningful use because we can't agree on the value sets within HL-7. Those often have to be determined. And you wind up with different value sets within different countries. Point number one is that the absence of global vocabulary standards makes it very difficult for HL-7 international to produce fully defined, fully articulated, global standards.

Point number two is that value sets need to be built alongside the exchange artifacts. Inevitably, when you have one group building the value sets, and another group building CDA documents or building V2 messages, when you try to line those two artifacts up together, there's always a little bit of wiggle room at the interface between the terminology and the information model. And we have certainly found that with the quality measures that we were developing within HITSP, we've found that in a number of other cases, HL-7 and IHT SDO have worked together to try to bridge some of this gap. But I think the main point here is that when we're thinking about value sets, it's very important that value sets and the exchange artifacts that will be carrying those value sets have to be built alongside one another if we really want to achieve at least what the vision of an integrated standard.

Point number three is that I believe we need to be driving towards integrated terminologies. I think value sets are ideally all drawn from a comprehensive, integrated terminology. At least, when I say the word integrated, I think back to a lot of the conversations, Chris, that you and I have had. I want to use the word virtually integrated terminologies.

If we look at value sets without also considering the extent of integration or federation of the source terminologies, I think we can wind up with less than ideal situations, and I think we can wind up having challenges with respect to decision support. And I have a couple of examples here. These relate to the fact that we might recommend the use of SNOMED for SNOMED findings for allergic conditions, and we might recommend the use of RxNorm and NDFRT for substances.

On the surface, here we are defining value sets. Well, you know, SNOMED is fine and dandy for findings, and RxNorm and NDFRT are what we're targeting. But if we don't think about the big picture, if we don't recognize the fact that because these are drawn from nonintegrated terminologies, the scenario that can arise is that Mr. Jones, let's say he's allergic to X. What we need to know from a decision support application is whether or not Mr. Jones can safely be prescribed why. If we look at the SNOMED hierarchy, we might infer one answer, whereas, if we look at the hierarchy that's afforded to us in RxNorm and NDFRT, we could come up with a slightly different answer. And so, I think here that point number three is that long-term, what we need to be driving towards is integrated terminologies.

Finally, point four is that at least the point that was brought home loud and clear through HITSP foundations was it is helpful to put a stake in the ground with respect to a value set, but it's also important that we take a deliberate approach to the real world challenges with adopting those value sets. Jamie, I know we've talked about these in the past, and I believe that, down the road, there may be a panel set up whereby implementers can speak to their real world value set adoption challenges so that that will give us the opportunity to come up with a set of recommendations.

I do believe that it is really, it really is valuable for us to put a stake in the ground with respect to value sets. But the problem is, we can't be so naïve as to believe that just because we build it, they will come to it. We have to really understand what those impediments are, and we have to take a conscious,

deliberate approach, including recommendations often to ONC or higher if we really want to make the value sets that we recommend something that become widely adopted. Thank you very much.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Thank you, Bob. Now we'll go to Becky Kush.

Rebecca Kush – CDISC – CEO & President

I'm Rebecca Kush from CDISC, and Bron Kisler, who leads our terminology, happened to be in town for a terminology meeting, so I asked if he'd come by for the Q&A. Thank you very much for inviting us to present today. There is a written testimony, so I'm going to stick to some of the key points in this verbal testimony.

The length of time to conduct and translate research, including comparative effectiveness into clinical decisions takes far too long today, and this is a process that's in desperate need of improvement. At the core of an efficient and effective healthcare system is the ability to aggregate and compare adequate amounts of information, which requires standard formats, vocabulary, and value sets. In the written testimony, I gave two examples: one from FDA and one from the Critical Path Institute.

They were unable to answer their questions from a multitude of studies and sources because it wasn't in standard format, and they had to backwards map it into a standard format in order to answer those questions. As you all know, that's inefficient, costly, and fraught with additional error potential. CDISC, AHIMA, and the National Quality Foundation put forth in this written testimony the need to support a paradigm of collect data wants and reused for multiple purposes, including public health monitoring, quality metrics, clinical research broadly defined, and that's really a case of building the quality in upfront from the beginning. A key message that I'd like to leave with you is the need for these long-term requirements, which have to be clearly in the forefront when the plan for meaningful use announces the standards for value sets for the short-term.

Also within the written testimony that I provided, I presented the findings of an extensive stakeholder analysis that we did last July and August to determine the benefits, risks, business models, and current related work for a global, accessible, electronic library of data elements with precise definitions and value sets. Some of the key findings are listed in the written testimony. Just to go through three of them, there were over 70 participants from 50 different multidisciplinary organizations, and not one of them felt that this was not something that would be useful.

There is a real need for a reference value set. There are concurrent efforts going on actually being funded by the U.S. government to provide repositories, but none of them provides a reference value set. And the development of this repository should engage a broad set of stakeholder groups so that we don't just do something like we did with Medro, where we solved the FDA's problem, and solve it for the pharma companies, and then we have a one-off vocabulary. So we don't want to have that happen again, and we just as soon make this a global effort with a lot of stakeholder input.

Thanks to Don Mon, there's a diagram in the written testimony about the components of a collect once, use multiple times paradigm system, which are to have harmonized reference value sets, leveraging current work, an open global repository, a broad input into the requirements for the tooling, and governance, both at a high level for governing the overall process, and at a technical level for governing the value set creation. So there are also three questions that I answered that are an appendix to my written testimony. I don't have time to go through those now, but they are there. And the recommendations that we would like to put forth today are to convene an appropriate stakeholder group to obtain consensus and launch this initiative, and to establish a public/private collaborative to implement

the initiative, funding the four components of this paradigm for the repository, and leverage the current work, which would include the CDISC share work, the National Quality Foundation's quality measure work, AHIMS work with HL-7 to look at diabetes strategy as a prototype.

CDISC is a global SDO. It actually focuses on content, not transport, although we have an XML solution, but that's not our focus. We have a track record of leading collaborations, and CDISC, with its partners, AHIMA and the NQF and others, have done and are doing extensive work and analysis in piloting tools and harmonizing different value sets that can contribute, along with other good work, to create an open reference value set repository to accelerate the vocabulary taskforce and HIT standards committee's goals for the benefit of the nation, and we're prepared to do this. Thank you again for the opportunity to present today.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Great. Thank you very much. Next, we have Lisa Miller.

Lisa Miller – X12 – WEDI Liason

Thank you very much, Jamie. My name is Lisa Miller. I've been with X12, I think, forever. I'm also a nurse, so I come from a unique perspective to speak on these code lists. I'm not only from a clinical background, but also from the administrative background.

X12 was chartered by ANSI in 1979. We developed EDI standards and documents for national and global markets. We have more than 315 EDI standards, and we are moving forward with our increasing X12 XML standards.

X12 enhances business processes, reduces costs, and expands organizational reach. Our members include standards experts from healthcare, insurance, transportation, finance, government, supply chain, and other industries. Just as a point of reference, healthcare was the last industry to come to X12 for standardization and use of EDI.

X12 appreciates the opportunity to provide our input. The themes of our comments surrounding the subsets or value sets used to report health data must consider the following three things. The business use case should be the driver for what the subset and/or value set is developed and maintained. The subset or value set must be implementable.

It's been our experience that it's important to be mindful of the processes and the staff at the entry point of health data. Let's face it. If it's too complex, use of the data will be compromised, and they will make it not be complex. Don't reinvent the processes to develop and maintain the subsets or value sets used in healthcare data when organizations and processes exist today. Efforts should be made to have a single maintainer for each subset or value set used to report health data.

I'd like to highlight a couple of our responses. Who should determine subsets or value sets that are needed? It's our feeling that industry stakeholders from both an administrative and clinical perspective should be involved. The subsets and value sets must meet the business and use case requirements of the stakeholders. If for some reason there's a code list that is part of a standard, it is X12's position that it should not be decoupled from the standard. Specifically from X12's point of view, that's because we span more than just healthcare and insurance.

When determining who chooses the subsets or value sets, the following three questions must be considered. What if there is more than one list that exists? Who picks the preferred, adopted code list? And what if that list is currently in the standard adopted? We're lucky enough to be that standard that has

money attached to it and was adopted under HIPAA, so ours are actually out there and adopted, and many of our code sets are being utilized today.

X12 is continually reviewing our standard to meet new or modified business requirements that are brought to the committee by the industry. During these reviews, we may determine that X12 create an external code list, and it should be used rather than a fixed code list that's attached to the standard. Basically what that means is that we would have the ability to update the list, as needed by the industry, without publishing a new standard, if that makes sense to everyone. This evaluation is based on the frequency of changes to the code set, and industry demands for frequent, periodic updates to meet or modify business needs.

There's also a difference in our standard between what we consider an external code list, which is external to X12, meaning ICD-10, ICD-9, HCPCS codes, versus one that we maintain and then release periodically. A good example of that would be claim adjustment reason codes or remark codes that we actually do the maintaining.

Who should produce the subsets of value sets? Standards bodies, as well as code set maintainers responsible for that set with industry stakeholders. Without the industry stakeholders, you won't be meeting the business need required by the subset or the value sets.

Who should approve them? The code set maintainers must work in an open, transparent. The SDOs working in a consensus and collaborative process, and then industry stakeholders, which may or may not participate in the SDO or code set maintenance group. So you must reach outside of the SDOs to reach your stakeholders. They may not be at the table at the time. So we must involve those as well, as well as working collaboratively, as John spoke about with the SCO.

How am I doing on time, Jamie? Pretty well.

Do you have any other advice or comments? I'd like to close with meaningful use rules provide the industry with a new set of business and use cases, which correlate to the promulgation of the HIPAA rules. It is critical that the industry consensus drive the development maintenance of the subset or value set that best support the business and use case. The lesson learned by X12 in creating the implementation guides adopted in the HIPAA rules is the importance of creating unambiguous implementation guidance and documentation for the reporting of health data for required business purposes. Thank you.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Great. Thank you, Lisa. And next, we have John Klimek from NCPDP.

John Klimek – NCPDP – VP Industry Information Technology

Thanks, Jamie. First, I think we have some slides up that I'd like to just try to make sure I keep track of where we're going. First, the first slide pretty much tells you who NCPDP is. We're an ANSI accredited organization that provides a forum and marketplace for diverse membership. Also, it's a member driven organization that has been named in various government regulations and policies.

Next please. This just gives you a brief overview of our membership representation. We have basically three categories: producers providers, payer processors, and vendors and general interest. You can see within each of those categories, there's a host of players that come to our meetings and have input into our standards.

Next please. What I've tried to do is break out each of the questions. The written comment was actually derived from our members, and actually written by Lynn Gilbertson, our VP of standards development. So the comments that I'll be presenting were actually coming from our members.

The first one is who should determine subsets and/or value sets. We fully believe that it should be industry driven, as what was previously talked about earlier, all throughout today. Also, the enhancements are business driven in the collaborative environment, and then there should not be any confusion. We just listed one with the drug concepts example, which would come from RxNorm, the strength from one vocabulary, the route of administration from another vocabulary. There has to be some clear guidance there.

Next please. Then who should produce these sets and subsets? Again, owner operator responsible, again, which was talked about earlier today, timely and then quick access, a possible common site of distributorship.

Next please. Who should review and approve the subsets? We can't say it enough, industry input, and then also rule-based.

Next please. How should the subsets or value sets be described? We listed several examples there. First of all, they should be clearly established. Examples meet the criteria, and that the possible metadata for value sets would be the subset name and identifier version or revision identifier, access information, update frequency, source information sets, version/revision, source information set owner, and then also subset, value set, definition authority, so with those examples.

Next please. What format? Again, they should be distributed in a consistent manner. Some examples were mentioned earlier today such as Excel or CSV or tab limited. Again, those are the popular choices that we see today. There could be others.

Next please. How frequently should subsets and/or value sets be updated, and how should updates be coordinated? Again, we can't stress enough, timely, especially in the pharmacy world. New drugs hit the market just about every day. We want to make sure that there's timely access to that information. And, if possible, prior to industry need, if that's even remotely possible in the drug world. Both value sets and subsets, the same schedule for consistency, and then possible schedules posted with customer support for questions and comments.

Next please. What support services would promote and facilitate their use? Again, educational information on the use of the products, distribution schedules, published production distribution schedules, ease of access to obtaining these products. Again, like mentioned earlier, customer support to handle general industry inquiries, account management functions for timely support of technical and business users, and then ease of access to request enhancements or modifications to the subsets. Examples would be something very similar to how NCPDP handles requests from our members coming in looking for industry needs. Then escalation procedures for emergency needs, if that's at all possible.

Next please. What best practices, lessons learned have you learned? What problems have been learned to avoid regarding vocabulary subset and value set creation, maintenance, dissemination, and support services? Terminology organizations are the best source of this information, industry buy in, of course. The best example is the NCPDP external code sets, which updates quarterly. Lisa mentioned earlier about them following a similar procedure of having an external code set, which we update quarterly, and basically we don't have to then wait for a new version to be released of our NCPDP

standard. We depend on this external code set as being updated on a regular basis. And then driven by industry needs, and then also and, I guess, most importantly is timely.

Number nine, next, do you have any other advice or comments on a convenience subset and/or value sets and their relationship to meaningful use? I guess, in the pharmacy world, we're still a little bit unclear as to how this plays a part in the pharmacy world, although the RxNorm obviously is a clearer value set. Industry requesting caution and experience for vocabs listed.

Number ten please. What must the federal government do or not do to regard to the above and/or what role should the federal government play? Most importantly, obviously, is provide clear guidance on the gap between terminologists, message exchange, and implementer. As was mentioned earlier, alphabet soup, we deal with it every day. And then possible diagrams for the implementers. That, I think, is it. Thank you very much.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Great. Thank you very much, and thank you all for your testimony, both written and in person here or on the phone. I'm just going to kick off with essentially the same question that I first asked the last panel of terminology service providers, but with a slightly different flavor. We heard very much from the EHR vendor panel this morning, the need and a preference for having a central authority to manage processes for determining and disseminating terminology value sets and subsets, and that that central authority should have both regulatory authority and a source of funding to pay for what's being requested. My question for each of you is what relationship should SDOs have with that central authority?

M

Do you want to start with Bob?

Bob Dolin – HL-7 – Chair Elect

Sure. Jamie, I didn't go through all of my written responses. Question number one, I think, two and three tried to get at the heart of who should determine what's in these subsets or value sets. My own feeling is that it needs to be done within a standards development organization. Therefore, there has to be a relationship between that standards development organization and the central authority.

The central authority is not necessarily the standards development organization because this value set machine, or this terminology machine, there might be expenses associated with it. But I do think that the SDO is the best place. One of the reasons for that is because we're not just building value sets for quality measures.

I mean, we really want to make sure that the value sets that we're building for quality measures aligned with and are equivalent to, and reused across clinical practice guidelines and decision support. That's really what it's going to be. That's really what it's going to take if we're going to have meaningful use. And so there's a need to have various groups come together.

I do not believe that value sets should be developed within IHT SDO, and I do not believe that value sets should be developed within LOINC because I think that if we do that, we're going to wind up having multiple value sets for the same purpose. So I think that the SDOs, such as HL-7, which is my preference, would be the best home for the development. That doesn't necessarily mean that they have to be the place where everything is housed. I think the NLM has done pretty amazing work with making terminology available to people within the U.S. And that is fine as ... model. But that's different from the governance model for what determines the changes to the value sets.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Thank you, Bob. Other responses?

John Quinn – SCO – Chair-Elect

I'll build on Bob's. Clearly the domain experts for any given area of medicine are either working in HL-7, or some of them are working actually more in IHT SDO than in HL-7, and some of them are working in NCPDP, and we can go through the various SDOs. There's probably, I would believe, looking across the landscape, there would be some benefit to actually some coalescing occurring.

I am a little concerned about, I mean, I am on the IHT SDO listserv, and I see all the conversations going back and forth. We have a global set with IHT SDO, and obviously the reference organizational structures of SNOMED itself. But the actual value sets, I mean, my concerns are the value sets themselves that are in use in the U.S. are, right now, diffused across an awful lot of different individuals, kind of working individually. And that's good as long as there's some sort of central authority as to who is determining what's being accepted.

I am very concerned that what we are dealing with really is the knowledge of medicine. Quite frankly, I look at this as a semantic web of the knowledge of medicine, when you take a look at what terminology means and that's how we encode the science of medicine.

The science is ever changing. It's changed massively in my lifetime. It's accelerating in change. This is not like coming up with the code sets necessary for my bank account and other IT endeavors. I think it's the one thing that actually most distinguishes what we're trying to do in healthcare as to what has happened in IT and other industries is specifically this issue of terminology where we embody medical information.

Changes that are made that are not coordinated, and in my written part, I actually come up with a couple examples of this. You're going to likely end up hurting somebody, okay, because if an update is made, and not everybody updates at the same time, and they don't update together, the receiver of newly coded data is going to get, at best, undefined, and at worst, a bad guess. And the physician made indeed then react inappropriately with a negative outcome. I think we need to think of this as this is the embodiment of medical knowledge, and it changes a lot, not just because we have to do updates for technology, but because medicine changes every day, at least if you get any of the journals.

Lisa Miller – X12 – WEDI Liason

Jamie, I'd like to build on this a little bit. We feel that the government should be the industry stakeholders' arbitrator when we have more than one subset or value set that's owned by or replicated by another organization. But I agree with everything that John said as far as we're going to have a bad outcome. But remember that from X12's perspective, we end up with the administrative part of it, which is the financial end of it. And what you have happen in that clinical setting, and how you report it, then has a financial impact at the end of the day as well.

There needs to be coordination between that clinical and administrative subset and data set. But, at the same time, we have to know what's already out there as an install base, what people are utilizing because, at the end of the day, if people don't have their claims paid for, they're not getting accurate information, even worse, they're going to get blocked from care. The government really should be that arbitrator.

As far as a single place to go get them, it depends. We don't want them decoupled from the standards. We build messages based on use cases, based on a business need. When someone comes to us, and

they say, we want a new message, the first thing we ask is what's your business case. What's your use for this? Those value sets, those data sets that are put inside of there have business meaning, so it's not like we're creating these just to create a new set. It meets the business need, and not always will the government tell us that, but we do believe they should be the arbitrator. There has to be kind of the traffic cop saying this is adopted, or this is not adopted, very much like HITSP was going through and saying, you know, for eligibility, that's a 270, 271. Sorry for the alphabet soup, but giving guidance to the industry of what those messages are, and then what are the appropriate data sets that we use and value sets inside of them.

John Klimek – NCPDP – VP Industry Information Technology

Yes. I'd have to agree with everything that was said. In the pharmacy world, again, through my presentation, I couldn't stress enough, timeliness. It's frustrating for a pharmacist to be trying to dispense a medication only to find that they don't have the right code or the right NDC loaded, either in their system or in the system that they're trying to communicate with. To me, that just puts a damper on the patient even getting the medication. I think that, along with obviously making sure that everything else works correct, and then that's always been my major concern.

Rebecca Kush – CDISC – CEO & President

That's obviously not a simple question, and I think that what we should be doing is putting together this public/private partnership, having this be a collaborative effort. I don't think any one SDO is in a position to take this on because we, right now, have dueling standards as it is. And I think we need a process that's very streamlined in order to do this.

One of the things we proposed is to have a group agree on at least a very core, fundamental set at the atomic level from which you can build a number of these use cases because, if you keep creating a standard for each use case, then it's not ever going to be reusable for another one unless you look at the atomic level and then build the molecules up from that. So I think we need a group that can agree on a core set of elements. We've done that with the FDA and a number of other groups with a global standard and a set of value sets that NCI and CDISC have agreed on. They're now in the EHR clinical research HITSP interoperability specification, and it is a core set of information that's needed across all research studies.

Two years ago, people thought that wasn't feasible, and it's done now. So need to look at that and see when foundations and everything starts over and starts harmonizing, why can't we look at what the work has already been done on a global basis with harmonization across NCI, HL-7, CDISC, through the Joint Initiative Council, as a global core set of standards and say, what can we not live with ... some of these core standards, and leverage the work that's been done before we start over again?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Yes, Bron?

Bron Kisler – CDISC – Director of Terminology & Strategic Alliance

Just to add one thing to that. So I think it is important for federal agencies to collaborate and partner with the standards development organizations. Becky referred to the example of the FDA. I think the reason the FDA likes partnering with CDISC is because we have a much larger access to much larger community.

We're kind of like this collaboration nexus, so we can work with the FDA on a standard. But sort of through the CDISC process, they can also work with industry global pharmaceutical companies. They

can work with technology vendors. They have access to academic institutions, foundations, and professional societies. And so I think it's important that that partnership continue.

And, like Becky said, I don't think it's any one standards organization. I think it's the federal agencies working in collaboration with multiple standards organizations.

John Klimek – NCPDP – VP Industry Information Technology

Yes. I'd just have to make another comment. That's absolutely true because, within the last five years, we've had much closer work with FDA, CMS, coming to our meetings, understanding our workload and exactly what their needs are, trying to understand their needs, as well as them understanding our needs, so that collaboration has just grown within the last five years.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Great. Thank you. Chris, a question?

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards

Thank you. As an observer of this community, I've been impressed with the coordination and complementarity that works across your organizations. I think it's continued to mature, and is a testimony to your, I think, mutual commitment to do the right thing.

That being said, one still finds oneself with a notion of some degree of siloing. If I can be overly reductionist, I can characterize messaging. I can characterize clinical research, insurance, pharmacy, down the line.

To pick on a specific, while NDC code may be really superbly suited for supply chain and related activities in pharmacy, arguably it has issues with decision support, and we could make all kinds of permutations. There's this holistic goal that is manifest across multiple domain use cases. I think this is the point you were getting at, Becky. How do we, as a community, as a committed, I think, consortium of well-intended organizations, realistically transcend the domain use case specific needs that drive the business cases that you all confront in a way that allows the common reuse of this information for purposes that are, quite frankly, outside the domain of the SDO development? Hard problem.

Bob Dolin – HL-7 – Chair Elect

Chris?

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards

Yes, Bob.

Bob Dolin – HL-7 – Chair Elect

I believe you're painting a nice picture for at least a virtual integrated terminology.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards

Where have I heard that?

Bob Dolin – HL-7 – Chair Elect

I think you just came up, I mean, we have had a lot of nice discussions about, you know, way back when about federated versus integrated. And you certainly swayed me with some of the strong advantages of the federated model. As we had subsequent discussions about this in HITSP, we began realizing that you can have, in some ways, your cake and eat it too. You can have the benefits of the federated model whereby, for those areas of the terminology that require a certain level of editorial control or that require,

for instance, a particular turnaround time, you can have that, but so long as all of these different terminologies are operating within the context or, to the extent possible, operating within the context of a shared concept model, you can at least present to the implementer a virtual integration.

I think, at least to some extent, this gets at your issue of siloing where I want to use an NDC code for a supply chain, but then how does that roll up to some of the broader concepts that I need to insert into my decision support rules. I think you're actually painting a pretty compelling use case for the need for at least a virtual integration model for the overarching terminology from which these value sets are drawn from.

John Klimek – NCPDP – VP Industry Information Technology

If I can just make a small comment, I mean, what you describe, Chris, is what NCPDP tried to do two years ago in the development of the Standards Charter Organization. We saw silos out there. We saw us working in our pharmacy silo. We saw other silos happening out there, so that was the premonition of the SCO to try to come together and try to bring down some of those silos, try to work more collectively together to try to prevent that from happening. I think we've made some of that, although, again, we're just adding another quarterly meeting onto another quarterly meeting that everybody has got to meet. And it gets difficult to try to address as much as what's being described here. I think, again, that's part of our challenge.

Lisa Miller – X12 – WEDI Liason

Chris, I think one of the most important things is that the member organizations that are here on this panel actually self-identified two years ago exactly what you said, and we acted upon it without the world coming and saying you have to act on this. So for the first time, I would actually say we were not reactive. We were proactive, and that's a huge step in the right direction when you look at the members of this panel that we're here shoulder-to-shoulder, and on that SCO to move this forward so that, at the end of the day, if someone comes along and says, you know, this is the code set, value set.

X12 can look at it and say, okay. We're now going to reference that, and it's now referenced by this data element, and we put it in our next message or our next versions of the standard so that we do have that interoperability, and we do talk the same language. So we have the outcome that we want at the end of the day, which is safe patient care, accurate reporting, and the lovely lady that kept saying data, data, data. I can't say it enough, but the data has to be clean because you can't have a mismatch between that clinical data—now my nurse's hat is coming on, right—and that administrative data because, to clean that up, from a patient perspective, from a physician perspective, is a small nightmare.

And you have been all talking about, you keep bringing up my favorite topic, which is diabetes. My daughter is a Type 1 diabetic. She had a misdiagnosis put in her record. They denied her some of her coverage. It's taken me nine months to clean that up. That misreporting is really what we're all here about and to move that forward. So you talk about something near and dear, and I do want to say this. ADA is Type II. JDRF is Type 1. I just want to get the domains right. Okay. Now that I've said that, I'm much happier.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Do you want to say something, Bron?

Bron Kisler – CDISC – Director of Terminology & Strategic Alliance

CDISC, in our mission statement, we're very committed. You know, we understand. We have the clinical research, regulated clinical research community, which are our primary customers. We're also very committed to understanding the connection between our work and the healthcare and patient care

environment, and we've tried a number of different approaches to kind of break down the walls and the silos, develop the bridge model. You know, we're looking at development of a share repository.

But probably one of the most successful things that we've done that really breaks down that silo is doing work around a specific disease. Just as an example, we worked on an NIH project for tuberculosis. And also when you're working on tuberculosis, and because you're focusing on a specific disease, it brought multiple standards organizations together. It brought global federal agencies together. It brought CDC, FDA, three divisions of the NIH. The different approaches that we have tried in sort of breaking down those silo walls, that's probably been the most effective that we've seen to date.

Rebecca Kush – CDISC – CEO & President

And I'll just add that now the FDA is coming to us and asking us to take our standards, which cover the safety domains, 18 safety domains that cut across all studies, and add all the therapeutic area specific standards, and we would prefer not to do it the way we Medro was done before my time of getting into this. We would really like to make sure that it works in a broader community. And we've held up a lot of the progress on that in order to try to engage a broader community.

That's why we're here today to try to make sure that this is done in a collaborative way, and to make sure research and quality and public health all can be taking data from the same clinical source in a very easy way. So we need a process that's streamlined. We can't have every SDO out there doing it a different way. And we've seen that through the Joint Initiative Council. We're getting better, and we're getting there, but we're trying to harmonize processes across SDOs, and that's an interesting exercise.

John Quinn – SCO – Chair-Elect

I'm not trying to be too contrarian, but you open up a black hole of unintended consequences. On the one side, I agree with you. On the other side, I'm thinking about all the people that objected to how complex and too complex XML is, and our messages are too big, and the audit trails are too large, and the NHS is sinking in SAN storage because their legal requirements of holding audit trails for all their messages that are so big, that while it is a good objective, and everybody on this panel wants to say yes, we should be able to support all these unexpected uses of data at a later time. It does not come cheap in terms of the impact it has on the size of the schemas, the size of the messages, the size of the documents that not only just have to be transmitted, but store. And if they're going to be available for later reuse, then those schemas need to be there.

I like to use the example that 99.99% of the time when you're looking a blood result, a test result, you're not interested in the revision number of the firmware on the blood analyzer and who was the last technician that worked on it. However, if you're later trying to do a study on what ends up being the equivalent of a Toyota recall on why do we have problems with this particular set of bad results being pushed around, then in fact that is how you will easily get to it in your quality research. So there's a price to pay.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Thank you very much. Now I have a question, and then I believe Clem was next, and then Chris. My question is specifically for Lisa and John for X12 and NCPDP. It is that both of your organizations have standards that have been adopted in legislation and regulation, and both of these are message standards that are used for transactions that carry monetary value and have payment associated with it. Yet, you said essentially opposite things in terms of how value sets should be externalized versus developed internally within the development of a particular message.

And so Lisa, if I got you right, you're saying that essentially, from your perspective, it's important for the value set that's used in a particular use case to be developed along with the content exchange mechanism so that the binding is understood, and everything works, is really implementable. And, John, you said that it's important to externalize the development of the value sets because medication data changes so frequently that you couldn't possibly maintain updates to the message, and so you have to have a binding mechanism that can manage that level of change. The fact that you both gave essentially opposite answers on that point, does that just mean that we have to have a mechanism that accommodates both of those, or is it possible to find a different way that you both could use?

Lisa Miller – X12 – WEDI Liason

Jamie, I'll actually go on this one first. A little bit of a lesson here, and I'm going to put on my hat as the soon to be chair of the communications and control subcommittee for X12. We really have three kinds of value sets or code lists. One is internal to our standard. I want you to think of that as something that's structural, that if you took it away from our standard, it could potentially create a very big problem.

At the last X12 trimester meeting about four weeks ago in Seattle, we actually held a session on decoupling value sets, code lists from our standards. What we walked away from is, you know, we're not really sure that that's a good idea. Let me give you an example of one of those.

If you look at our structure of our standards, we have something that looks like a sentence. And, in that sentence, we have something that gives it a flavor crystal. So I could have an NM1 sentence or segment that, in one case, is a subscriber. In the next case, it's a provider. And it's the code in the very beginning of that segment that says I'm declaring what I am. That particular one is structural to X12.

Versus another kind of value set that's owned by X12 that we're actually going to decouple from the versioning of the standard. A great example of something along those lines would be service codes, CARC and RARC codes, claim adjustment reason codes or remark codes where we version those three times a year so that people can come to our standards body, sit in a committee, say I have a new business need, and we don't have to publish another version of the standard.

If we decoupled, and those are both internal and maintained by the SDO, if we decouple completely, we now have to start telling you what version of those codes potentially we're passing, which means not only are we going to tell you what implementation guide, 004010XO98A1, B1, C1, whatever flavor of the day we have. We're also now going to have to tell you what version of those codes we're going to pass to you as well, because some of them are structural to the standard, and they may not have been included in previous versions of the standard. All of a sudden, we exponentially create an unimplementable thing, so that's why we first said it must be implementable.

The third kind of code list that we may have is completely external to the SDO, and my best example of that, and I did want to bring this up, which is ICD-9, ICD-10. We certainly reference those because, if you're going to pay a claim, or you're going to ask for a claim, you're going to put a diagnosis code in there. We now support ICD-10 in our next version 5010. The only thing we really had to do in that versioning is, we needed a new qualifier that said this is ICD-10.

And the only reason we needed that is, at the time we published our first standard, ICD-10 didn't exist. So we added a code. We published our standard. It's internal. We're saying this is the flavor crystal. Think of it like we're Jell-o, and we can change our flavor based on what we need from a business perspective. And we were able to handle that external code set.

We don't maintain ICD-10, nor would we want to. It's outside of our purview. And while I mention that, I just would like to caution this group. I just explained a really great business case where we, as a standard, supported moving from one thing to another. But the implementation of that, if no one else has heard of this yet, is rather large and getting a lot of traction, and millions of dollars being spent towards moving from one coding system to another, and it's becoming a big issue. We all agreed on it, but once we make these agreements, we now have to implement them.

It's, be careful what you ask for. You just might get it. We had to move to ICD-10. Our standard supports it. It was simple for us to support. It's an external code list.

Jamie, back to you, we support three different types, and it was even something, as we were putting our testimony together, we had to come forward and say, look, we really have three kind of different codes: two that are maintained by X12, one that versions with the standard, one that's not versioned with the standard that conversion in between standard releases, and then an external one, which gives us our third, so we can be very accommodating to this harmonization effort.

John Klimek – NCPDP – VP Industry Information Technology

All I can say is ditto. In looking at our versions and implementation years ago, we looked at if we were stuck to one version of external code lists, we were stuck with that for probably two, three, four years, if not longer. And again, going to what Lisa just mentioned about cost of implementation, there's no way that we could sell to our members, that they would have to make a version change every year. So again, external code lists were our top priority, and that's why we saw some value with that.

Again, looking at value sets that outside of our standards, again, Lisa mentioned CPT codes and ICD-9 codes. Those are all values that can be inserted into an NCPDP standard, along with NDC number and RxNorm codes. Those are all external codes. By no means do we want to manage that other than the fact that if there's a version, if there's a change in that, then we want to make sure that our members are aware of that as well. Again, that's where we're coming from.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Great. Thank you very much. Clem?

Clem McDonald – Regenstrief – Director & Research Scientist

I've got two questions. One is to you, Bob. You described trying to bind code sets or tie them in the SDOs and HL-7 was your favorite, and I like HL-7 too. And I think I heard other people saying something like that, that if you got a field in the message, you want it to have the right stuff in it, so it might be best to have the message developers at least tightly attune to that.

But do you mean that also for things like survey instruments and questionnaires that kind of come with the package, and they're not really – they're code value pair things like glass glaucoma score or the CAM, which comes as copyright. You can't, I mean, or would you want HL-7 to screw around with the answer lists to the CAM? I guess I'm begging the question.

Bob Dolin – HL-7 – Chair Elect

Sorry. I was on mute again. The minute the words came out of my mouth, I anticipated the question about the glass glaucoma scale, and I think you're right that in many cases it's HL-7's role, or it's the terminology developer's role to simply go ahead and formalize these things. On the other hand, we have a lot of experience where professional societies give us a form that they want encoded, or they give us a practice guideline, or they give us a quality measure that they want encoded, and we do bump up against challenges where we can't precisely formalize what it is they're looking for.

I don't know that I would pain the picture completely to the left or completely to the right, and I certainly didn't mean to say that there's not a key role early on the process for the professional societies to really define what it is they want. But I don't know also that I would want the professional societies to think that they could hand something over to LOINC or hand something over to HL-7 and say, here you go. My part is done. You guys go ahead and run with it. I think, in situations like that, the more you can have the professional societies and the standards developers working together throughout the process winds up leading to a standard that more accurately reflects the intent of that domain experts.

Clem McDonald – Regenstrief – Director & Research Scientist

So it's what we heard earlier that it is complicated. But I also had a question for Rebecca. I read over the document, and you talked about this cooperative group. I mean, you're really talking – well, I don't want to put words in your mouth, but you want to replace the current code system for recording adverse events. Is that what you're really saying? I don't want to – I mean, it may be a bad thing to say. Let me take that away. Let me take away that question. Let me jump to the next question. Why don't you just use SNOMED?

Rebecca Kush – CDISC – CEO & President

You know, I've asked that for years, and I know Chris has, and so has Betsy, and what I found out is interesting that what happened is when the ICH decided it was going to be Medra, then all of the pharma companies switched to Medra because that's what the FDA mandated at the time. And once you make that switch, you build all your systems around that, and then you have the ways of detecting signals. And if you switch in the middle to another coding system, there are all sorts of legal issues and everything else around trying to make sure that if your signals aren't showing what you think they are, that you're not going to be liable. And you know how they are, so I decided not to take it upon myself to try to change that whole issue.

But I don't want to repeat it again when we look at therapeutic area standards. And I think, when you're talking about—I believe this is related—when you're talking about looking at certain scales, we've started working with the Critical Path Institute on their coalition against major diseases. And they've managed to get databases around Alzheimer's from a number of different sources. Now they're trying to model that disease and see if they can look at new therapeutic affects and biomarkers and that sort of thing. And what they're finding is, across all those six organizations or 12, however many they collected, they're not using the standard scale the same way.

What we're really talking about isn't just a set of code lists. It's a very defined way of defining each field and how to put the concept together in terms of doing those therapeutic areas, and we have an opportunity here to do that right this time and not repeat the Medra mistake that I don't know how to solve at the moment.

Clem McDonald – Regenstrief – Director & Research Scientist

Life is hard.

Bron Kisler – CDISC – Director of Terminology & Strategic Alliance

Can I ask ... and also on the SNOMED, so when CDISC first started the terminology initiative, we had a number of standards that were already in the marketplace being implemented around the world. Several regulatory agencies said, okay, CDISC. We need controlled terminology value sets for your current standards. So when we started down that road about four or five years ago, we had talked with many different organizations, including the SNOMED organization at the time.

At the time, they were licensing incumbrances where we couldn't rule out our terminology value sets globally. Since those barrier incumbrances have come down, thanks to Chris. I'm getting CDISC together. So you have two equations. We have the legacy silos, right? We have the way we've all done things the past four or five years. Then we have the future. How do we go forward in the future and all learn from what we've done in HL-7, CDISC, and regulatory agencies and move forward together?

The question is, I think what you're asking, can you do that towards a single code system? This gets to Bob's, is it a federated system? I don't know what his other word was.

Clem McDonald – Regenstrief – Director & Research Scientist

With your specific space, it's got a lot of symptoms, findings, and all the rest that I think you've got a good – you don't have to get really worried about it. You're still going to have NDCs. You're going to have different countries that have different, and all that other stuff, and we'll have different drug codes. But you have one space that looks like a good bet for that kind of stuff.

Bron Kisler – CDISC – Director of Terminology & Strategic Alliance

And the other aspect that was important to CDISC at the time, we did not want to become a terminology organization. We did not want to be in the terminology business. There were enough people doing that, so we needed to find an organization with the resources and infrastructure and the capability to provide all that terminology expertise and support that we needed. The resourcing and the services around that was very important to CDISC.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Thank you. Any other questions here in the room or on the phone for this panel? Okay. I want to thank you very much. Thanks for coming. Thanks for participating.

M

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Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Yes. Before we go to our public comment period, I would like to just have a little bit of a reflection here on the taskforce of what we've heard so far today. I think we've heard a consistent message that some clear ownership of process is needed, and that's going to be true regardless of the centralization or decentralization of repositories and distribution mechanisms. We've also heard a need for making things implementable, making them real, and in fact testing regardless of which way we go with value set repositories of testing with at least one initial repository to make sure that the value sets for meaningful use can be disseminated through that kind of a mechanism. Are there other reflections on what we've heard here today that others want to touch on?

Betsy Humphreys – National Library of Medicine – Deputy Director

Another point that I think has been made several times in different ways, which is well taken, is that there are existing implementation services, organizations, agencies that have some experience with distribution of subsets and value sets, or repositories and so forth, and that we obviously want to go forward in light of the experience, best practices, problems solved that have already been handled by these various organizations of which there are some in federal agencies and some privately as well.

Bob Dolin – HL-7 – Chair Elect

Jamie?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Yes, Bob.

Bob Dolin – HL-7 – Chair Elect

So I'm cheating because I testified, and I'm on the panel. I guess the one message that I tried to make was, we have to think about value sets in the broader context of where we want to be with interoperability over the next several years. Meaningful use requires data reuse, and we have Chris' siloing scenario. I think that while our focus here is on value sets for meaningful use, if we don't address some of these bigger challenges, we may come up with a solution that isn't taking us incrementally towards this vision.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Thank you, Bob. If there are no other closing comments, and I want to thank everyone, both on the taskforce and in the room, and all of our witnesses. Then our next step is to take public comments.

Judy Sparrow – Office of the National Coordinator – Executive Director

Right. Yes. This is the public comment portion of the meeting. Anybody in the audience who cares to make a public comment, please queue up at the microphone, and state your name, your organization, and please keep your comments within a three-minute timeframe. And also, on the telephone, if you wish to make a comment, if you just press star, one. If you're on the Web, if you dial 1-877-705-2976, the operator will put you in the queue. We'll begin with the first gentleman at the phone.

M

My name is ... and I'm a Northrop Grumman contractor for Centers for Disease Control, and also a co-lead for vocabulary ... community of practice, so ... actually we have an opportunity to work with the implementers, the public health departments, and the SDOs, and also with the programs who receive the data and do the data analysis. I just want to thank you for the taskforce to really provide this opportunity to actually bring everybody together who would be involved in the vocabulary and messaging. I think we had the same opportunity, which Stan and Chris actually put together two years ago with a value set summit. I think we kind of – this seems to be a continuation of those things.

And I think one other thing I really wanted to point out that two years ago the thought that we thought was, we could actually take the definitions that it was put together during the HL-7 core definitions, and then probably maybe add it to the existing taskforce. Not all the details, but at least the basic terms like ... synonyms and ... mentioned. I think that'll be useful. And also, this actually has been discussed in detail during the HITSP ... data architecture, tiger technical committee. I think, without reinventing, we could actually even take those things. I think it'll be very useful.

I just wanted to give just a couple of just – I think the points that were discussed during the day, if I could address some of them or just provide some additions. One is actually the first one is really regarding the timing of the releases actually. So I'll take a scenario with the H1N1 where we had an H1N1 ... SNOMED ... released every six months, so we had to actually really have these codes within two weeks, and the SDOs actually provided the codes: SNOMED ... LOINC. So we actually had to inform the implementers about these H1N1 codes and all those things.

I think, in addition to ... releases on just a need basis, I think SDOs or even facilitators like NLM should facilitate these kinds of outbreak situations, which will really help adoption of the standards because, during the six months, now the H1N1 has been settled down, but during the six months, if you hadn't had that code, you would have ended up with the local codes from each public health department. So that's one comment.

The second thing is, I think CDC actually had – I think I was looking at the history. The first value set may have been created in 1995 for the HL-7 immunization guide. I think, during those days, the value set was really incorporated as part of the HL-7 tables or part of the implementation guide. I think, based on those things, one thing I really, even now today, the immunization guide, they're trying to upgrade from 2.3.1 to 2.5.1. The challenge is we still the same issues. Everybody has adopted easily the HL-7 tables. Now with the HL-7 2.5.1, we're trying to implement the ... standard and the HITSP standard for SNOMED, a simple thing, vaccination ... which is really about eight or nine codes. We couldn't find the SNOMED code ... we have post ... but it's very difficult for the implementations and educate them about all these advanced close coordination expression is quite difficult.

My time is over, I think, if I can continue one more minute, is it okay?

Betsy Humphreys – National Library of Medicine – Deputy Director

Sure.

M

And the other thing is I support the programs of various CDC programs and the public health department, so we have ... CDC value set repository ... we have about 600 value sets that support 16 implementation guides that's based on version 2x, version 3, and CDA. One of the things actually we really find is each implementation guide uses at least 30 to 35 value sets. It's really, you need a mapping tool that supports all these standards, not just one for LOINC ... and then SNOMED, a different tool. I think, for implementers, they need to have one tool that supports an implantation guide that could be facilitated by NLM, but just some of the mappings, and various other things.

One other thing I found very useful during the last five or six years with CDC is SDOs are really cooperating in providing a focused training, so when we had, for public health, LOINC, actually we used a subset of LOINC, which is really that's what we really focused on is microorganisms in ... lab. So we requested LOINC actually to provide a specific training for this group focused on microbiology and other things, so it was very useful, and the implementers were very happy with it. We had several questions, and then it really helped the interaction.

And I think the last comment I really wanted to make is, I think one of the comments from, I think, Floyd was when you have a value set that's being used by different programs. We have the same thing. We have one value set being shared by different programs. What we have is a version control in place. The implementation guide were designed whether to use the SNOMED ... from January 31st edition or from the previous edition, which is the July edition. So we keep all of them in the ... repositories, just the implementation guide drives the implementation. We don't want to create the same value sets for different programs ... explosions of value sets. Thank you.

Judy Sparrow – Office of the National Coordinator – Executive Director

Thank you. The next gentleman, please.

Tom Bizzaro – First DataBank – VP Health Policy & Industry Relations

My name is Tom Bizzaro. I'm a pharmacist and vice president of health policy and industry relations for First DataBank. For about 30 years, First DataBank has maintained and distributed vocabularies. I think that gives us a unique perspective on the vocabulary questions that are being raised now. Those vocabularies are widely implemented.

These are proprietary vocabularies that have been in our use in many HIT applications. Now we are looking to an interoperable future. I endorse that vision with a caution. The path to an interoperable

world must consider the impact of systems currently in productive use. Compendia like First DataBank created propriety vocabularies out of necessity. I would welcome access to timely, comprehensive, interoperable, national standard vocabularies.

Wherever the choice for those national vocabularies, the maintenance must be funded long-term. They must have frequent, timely updates. They should follow published, well-defined editorial policies. And, finally, they must be extensively tested.

These vocabularies should be available from a single site, and we've heard that comment made numerous times. I'm not sure that defining convenience subsets adds, or I think that defining convenience subsets may add an unnecessary level of complexity. I think it would be best to let the use case define the subsets that are necessary.

Healthcare has made great progress in the development of healthcare messaging standards, but within these standards, we speak many different languages with many different vocabularies. The necessity for a common language seems very clear. The question is how do we get there in a manner that most benefits the patient and the clinician. I thank the taskforce for the ability or the time to comment.

Judy Sparrow – Office of the National Coordinator – Executive Director

We have no comments on the phone. I turn it back to Jamie and Betsy....

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Thank you very much. I think that closes our meeting for today, and I just want to thank everyone very much for participating.